"COMPARATIVE STUDY OF FUNCTIONAL EFFICACY OF TRANS FORAMINAL VS INTERLAMINAR EPIDURAL STEROID INJECTION FOR LUMBAR DISC DISEASE"

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CERTIFICATE

This is to certify that the dissertation entitled **"COMPARATIVE STUDY OF FUNCTIONAL EFFICACY OF TRANS FORAMINAL VS INTERLAMINAR EPIDURAL STEROID INJECTION FOR LUMBAR DISC DISEASE"** is a bonafide record of work done by **Dr. SARAVANAN.B** in the Institute of Orthopaedics and Traumatology, Rajiv Gandhi Government General Hospital, Chennai, under the direct guidance of me.

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DECLARATION

I hereby, declare the dissertation entitled **"COMPARATIVE STUDY OF FUNCTIONAL EFFICACY OF TRANS FORAMINAL VS INTERLAMINAR EPIDURAL STEROID INJECTION FOR LUMBAR DISC DISEASE"** submitted for the degree of M.S is the record work carried out by me during the period of **March 2014 to September 2015** under the guidance of **PROF.N.DEEN MUHAMMAD ISMAIL, M.S.Ortho., D.Ortho.,** Institute of Orthopaedics and Traumatology, Madras Medical College, Chennai. This dissertation is submitted to the Tamilnadu Dr.M.G.R. Medical University, Chennai, in partial fulfillment of the University regulations for the award of degree of **M.S.ORTHOPAEDICS** (BRANCH-II) examination to be held in April 2016. This work has not formed the basis for the award of any other degree or diploma to me previously from any other university.

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Introduction

INTRODUCTION

Currently variety of non operative therapies for back and leg pain are available. They are simple rest, exercises, massage, heat therapy, traction therapy.

"Epidural steroid injections (ESIs) have been used as an adjunct in the treatment of sciatica. Since the early reports, success rates ranging from 18% to 90% (average, 67%) have been documented. However, the efficacy of ESI has lasted, on the average, less than 3months."[38]

In recent years, understanding of disc degeneration has undergone a significant transformation. Impairments of the back and spine are ranked as the most frequent cause of limitation of activity in individuals younger than 45 years old by the National Center for Health Statistics.[1]

Epidural injections in the cervical, thoracic, and lumbosacral spine were developed to diagnose and treat spinal pain. Structural abnormalities do not always cause pain, and diagnostic injections can help to correlate abnormalities seen on imaging studies with associated pain complaints. In addition, epidural injections can provide pain relief during the recovery of disc or nerve root injuries and allow patients to increase their level of physical activity. Because severe pain from an acute disc injury with or

without radiculopathy often is time limited, therapeutic injections help to manage pain and may alleviate or decrease the need for oral analgesics.

Epidural steroids are given by orthopaedicains, anesthetists, radiologists. Recent studies indicate that a high percentage of patients receiving the injections have significant pain relief and functional improvement. In a group of 70 patients with herniated discs in whom other conservative management had failed, epidural steroid injections provided significant pain relief and avoided surgery in 64% .Better outcomes were noted in patients older than 48 years and those who received the injections earlier (<100 days from diagnosis).

Few serious complications occur in patients receiving epidural corticosteroid injections; however, epidural abscess, epidural hematoma, durocutaneous fistula, and Cushing syndrome have been reported as individual case reports. The most adverse immediate reaction during an epidural injection is a vasovagal reaction. Dural puncture has been estimated to occur in 0.5% to 5% of patients having cervical or lumbar epidural steroid injections. The anesthesiology literature reported a 7.5% to 75% incidence of postdural puncture (positional) headaches, with the highest estimates associated with the use of 16- and 18-gauge needles. Headache without dural puncture has been estimated to occur in 2% of

patients and is attributed to air injected into the epidural space, increased intrathecal pressure from fluid around the dural sac, and possibly an undetected dural puncture. Some minor, common complaints caused by corticosteroid injected into the epidural space include non-positional headaches, facial flushing, insomnia, low-grade fever, and transient increased back or lower extremity pain.

Epidural corticosteroid injections are contraindicated in the presence of infection at the injection site, systemic infection, bleeding diathesis, uncontrolled diabetes mellitus, and congestive heart failure. Epidural corticosteroid injections are performed in a fluoroscopy suite equipped with resuscitative and monitoring equipment.

It is recommended the use of fluoroscopy for diagnostic and therapeutic epidural injections for several reasons. Epidural injections performed without fluoroscopic guidance are not always made into the epidural space or the intended interspace.

Even in experienced hands, needle misplacement occurs in 40% of caudal and 30% of lumbar epidural injections when done without fluoroscopic guidance. Accidental intravascular injections also can occur, and the absence of blood return with needle aspiration before injection is an unreliable indicator of this complication. In the presence of anatomical

anomalies, such as a midline epidural septum or multiple separate epidural compartments, the desired flow of epidural injectants to the presumed pain generator is restricted and remains undetected without fluoroscopy. In addition, if an injection fails to relieve pain, it would be impossible without fluoroscopy to determine whether the failure was caused by a genuine poor response or by improper needle placement.

Review of Literature

REVIEW OF LITERATURE

Studies done two decades back did not reliably establish the efficacy of epidural injections, because of the lack of well-controlled studies.

Riew et al[21] conducted a "prospective, randomized, controlled, double-blind study in: proceedings of the **North American Spine Society**, 14th Annual Meeting in 1999" showed early promising results of transforaminal steroid injection (TFESI) in lumbar canal stenosis.

Only in 2013 **North American Spine Society (NASS)** forms a work group to address following issues - efficacy of lumbar transforaminal steroid injection (LTFESI) in radicular pain and lumbar disc herniation, complications of transforaminal steroid , patients likely to benefit from lumbar transforaminal epidural steroid injections (LTFESI), reasonable maximum number of therapeutic lumbar TFESI that a patient should receive within a six month period to treat lumbar radicular pain, the value (eg, cost per Quality Adjusted Life Years) of TFESI in the treatment of lumbar radicular pain.

Hospital For Special Surgery- Spine unit in their study in 2002 of "Transforaminal Epidural Steroid Injections in Lumbosacral

Radiculopathy,[38] conducted a prospective RCT to assess the efficacy of LTFESI in patients with lumbar radiculopathy secondary to herniated intervertebral disc (HIVD). Of the 50 consecutively assigned patients, 25 received LTFESI and 25 received paravertebral trigger point injections. After an average follow-up period of 16 months, the group receiving LTFESI had a success rate of 84% as compared to 48% of the group receiving trigger-point injections. This study provides therapeutic evidence that for patients with herniated intervertebral disc (HIVD), LTFESI is more often effective (84%) than trigger point injections (48%) in providing at least 50% relief of radicular pain at 16 months".

A retrospective study comparing Interlaminar epidural steroids (ILESI) to Transforaminal epidural injections (TFESI) for symptomatic lumbar intervertebral disc herniations found that transforaminal injections resulted in better short-term pain improvement and fewer long-term operative interventions.

More recently, a number of randomized, double-blind, controlled studies have been done to evaluate the effectiveness of both cervical and lumbar interlaminar injections, as well as caudal epidural injections in the treatment of chronic discogenic pain with and without radiculitis. Overall

these studies indicate that a high percentage of patients receiving the injections have significant pain relief and functional improvement.

According to Campbell - In a group of 70 patients with herniated cervical discs without myelopathy in whom conservative management had failed, cervical epidural steroid injections provided significant pain relief and avoided surgery in 63%.

North American Spine Society (NASS) states **"**patients with lumbar scoliotic stenosis and radiculopathy experience significantly higher success rates after LTFESI if their symptoms were present for less than three months."

North American Spine Society (NASS) also states that "in patients treated with TFESI in the setting of disc herniation, effectiveness was more likely if the disc herniation was "contained" or abutted the nerve root and less likely if the nerve root was displaced or entrapped. The presence of stenosis, size of herniated intervertebral disc (HIVD), type of HIVD and hydration of HIVD do not predict outcome with LTFESI."

Studies have suggested the superiority of Transforaminal epidural steroids for both short and long-term outcomes.

A retrospective study by Schaufele et al[30] conducted in year 2006 assessing pain improvement and surgical rates for managing lumbar disc herniation between IL and TF injection over 18 months, reported TF ESI's superiority in short-term pain improvement and avoiding surgical interventions for long term.

Similarly Ackerman and Ahmad in 2007, "comparing efficacy of 3 fluoroscopically guided approaches (TF, IL, and caudal ESI) in their study demonstrated superior effect of transforaminal method of delivery."[31]

An advantage of TFESI is that it can be performed in patients with failed back disease.

NASS (North American Spine Society) also states "patients with radicular pain from an HIVD or central stenosis and/or lateral recess stenosis at the supra-adajacent intervertebral disc, obtain significant relief from a preganglionic LTFESI irrespective of age, gender, level of injection, symptom duration and pain intensity."

Gharbo et al[32] conducted a randomized, blinded, prospective outcome study which showed better results for ILESI may be due to midline Para median approach instead of traditional midline approach.

Traditional Interlaminar epidural steroids routinely given by anesthetists. But transforaminal approach commonly practiced by orthopedic surgeons and some well trained anesthetists, shows clear cut long term benefit also avoids surgical intervention.

Table 1 A : Head-to-head studies comparing TFESI vs. ILESI.

AUTHOR	YEAR	OUTCOME
Bogduk et al[2]	1999	supported usefulness of TFESI for disc prolapse
Riew et al[21]	1999-spine society meeting	Early promising results using TFESI in the treatment of lumbar spinal stenosis
Buenaventura RM, Datta S, Abdi S, Smith HS[33]	2009	TFESI superior than ILESI
Schaufele et al[30]	2006	TFESI superior than ILESI
Parr AT, Diwan S, Abdi[24]	2009	TFESI superior than ILESI
Rados et al [39]	2011	TFESI superior than ILESI

Bogduk et al[2] study in year 1999 supported usefulness of TFESI for disc prolapse.

Buenaventura RM et al[33], Schaufele et al, PARR et al demonstrated better outcome of Transforaminal steroids as they deliver

steroid directly over the inflamed nerve. Rados I, Sakic K, Fingler M et al, in their study in year 2011 at the end of 6 months found 28.3% in TFESI and 25% in ILESI as functional improvement.

However, some of the articles showing ILESI producing better results than TFESI. Such studies are,

Table 1B: Head-to-head studies comparing TFESI vs. ILESI

	YEAR	Functional Improvement TFESI vs. ILESI
Gharbo et al [36]	2011	43.6% vs. 49.3%
Kolsi et al[35]	JBJS 2000	34.8% vs. 50.9%
Ackerman and Ahmad [37]	2007	53.3 vs 60.6

Gharbo et al[36] study in year 2011, total duration of study was only 16 days.

Kolsi et al[35] in their study of "Efficacy of nerve root versus interspinous injections of glucocorticoids in the treatment of disk related sciatica. A pilot, prospective, randomized, double-blind study, **Joint Bone Spine** 2000' is also short duration study of only 28 days. Also participants were only 17 and 13in TFESI and ILESI respectively.

Aim of Study

AIM OF STUDY

- To compare efficacy of pain relief function of therapeutic transforaminal vs interlaminar epidural steroid injections for symptomatic lumbar disc disease patients.

- To assess improvement in functional outcome in lumbar disc disease patents after treatment

- To evaluate duration of relief and long term outcome after epidural steroid injections.

- To assess the quality of improvement in pain relief.

- To assess patient satisfaction after steroid injection.

RELEVANT ANATOMY

The human spinal column is an articulated segmental structure that serves dual purposes of protection and motion. The spinal columns functions include maintaining an upright posture, yet allowing for flexibility, while at the same time providing a conduit for neurological structures.

OSTEOLOGY:

LUMBAR SPINE

It consists of 5 vertebrae, which resemble each other structurally. The size gradually increases from L1 to L5. It consists of osseous and ligamentous structures

The block of bone on anterior part called vertebral body consists of compact mass of spongy bone surrounded by cortical bone. Vertebral bodies and the intervening discs, along with anterior and posterior longitudinal ligaments constitute the anterior and middle column of Denis. This bears 80 % of load in upright position.

A typical vertebra is composed of an anterior cancellous vertebral body and a posterior vertebral arch. The vertebral arch consists of a pair of cylindrical pedicles which form the sides of the arch, and a pair of

flattened laminae which completes the arch posteriorly. The articular processes are vertically arranged and consist of two superior and two inferior processes.

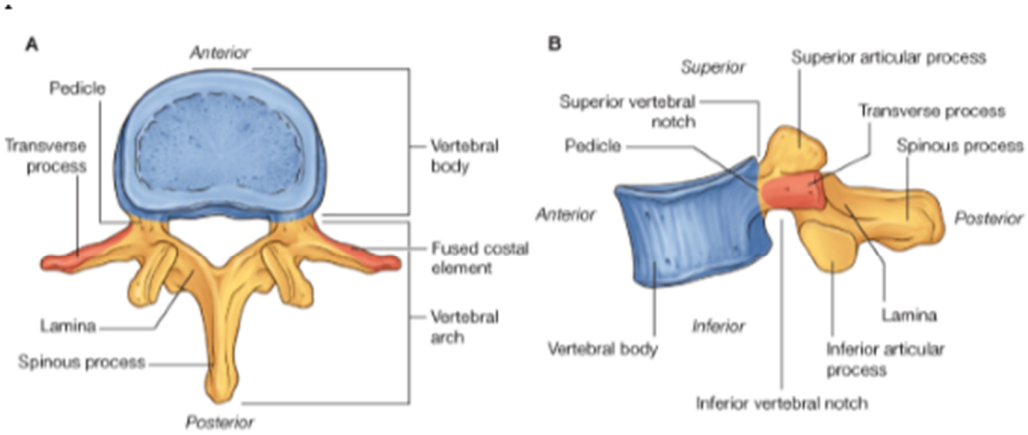


Figure :1 Osteology Of Lumbar Vertebrae

THE VERTEBRAL CANAL:

Boundaries

- Anterior wall- Posterior longitudinal ligament, posterior surface of lumbar vertebrae
- Posterior wall - Lamina, Ligamentum flavum
- Lateral wall- pedicle

Between the pedicles of adjacent vertebrae, lies the intervertebral foramen.

INTERVERTEBRAL FORAMEN:

The vertebral notches are located on the superior and inferior aspects of the pedicles of all vertebrae. The inferior vertebral notch is the most prominent and together with the superior vertebral notch of the vertebra below forms an intervertebral foramen, which are the exit points for the spinal nerves that leave the vertebra.

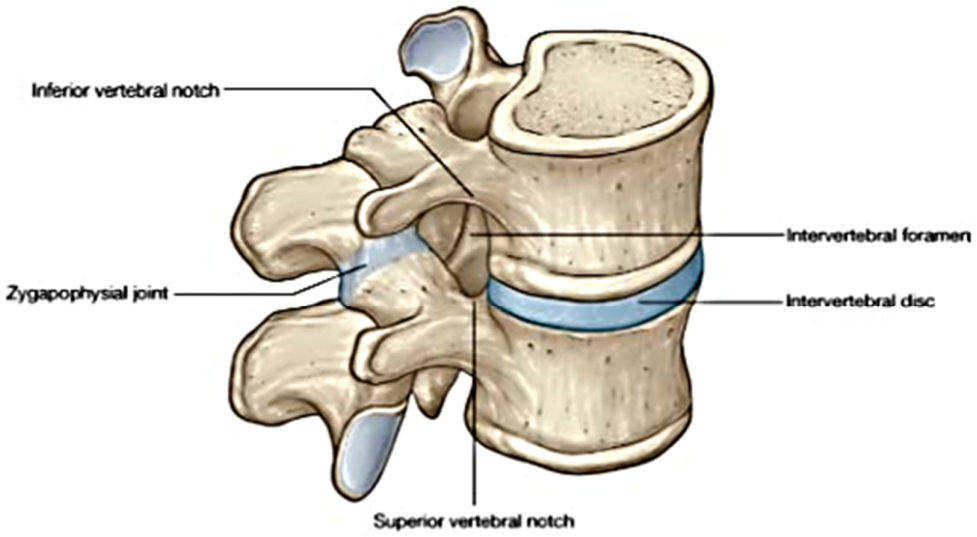


Figure 2: Joints In Lumbar Spine

THE INTERVERTEBRAL DISCS:

It consists of nucleus pulposus and annulus fibrosus. The fibrosus part is made of fibro cartilage, arranged in concentric circles. Nucleus pulposus is composed of loose, non-oriented collagen fibroid framework, supporting a network of cells resembling fibrocytes and chondrocytes. They are embedded in a gelatinous matrix of glycosaminoglycans and

water. The intervertebral discs make up approximately 25 percent of the total length of the vertebral column above the sacrum. In the lumbar region, the disc material makes up 33 percent of the length of the column.

At birth, the disc has some direct blood supply contained within the cartilaginous endplates and the annulus. These vessels recede in the first years of life, and by adulthood there is no appreciable blood supply to the disc. Over time, for reasons not well understood, the water content of the gelatinous nucleus matrix decreases, with a decreased and altered proteoglycan composition. These changes lead to a more fibrous consistency of the nucleus, which ultimately fissures. Blood vessels grow into the disc through these outer fissures, with an increase in cellular proliferation and formation of cell clusters. Also, there is an increase in cell death, the mechanism of which is unknown. The cartilage endplates become thinned, with fissuring occurring with subsequent sclerosis of the subchondral endplates. Herniated discs have a greater number of senescent cells than non-herniated discs and have higher concentrations of matrix metalloproteinases.

The normal adult disc has a large amount of extracellular matrix and a few cells that account for about 1% by volume. These cells are of two phenotypes: annulus cells and nucleus cells. The annulus cells are

more elongated and appear more like fibroblasts, whereas nucleus cells are oval and resemble chondrocytes. These two cell types behave differently and may be able to sense mechanical stresses. In culture, they respond differently to loads and produce different matrix proteins. The annulus cells produce predominantly type I collagen, whereas nucleus cells synthesize type II collagen. The characteristics of these cell types under normal and abnormal circumstances are beginning to be determined, and much is known.

The cells within the disc are sustained by diffusion of nutrients into the disc through the porous central concavity of the vertebral endplate. Histological studies have shown regions where the marrow spaces are in direct contact with the cartilage and that the central portion of the endplate is permeable to dye. Motion and weight bearing are believed to be helpful in maintaining this diffusion. The metabolic turnover of the disc is relatively high when its avascularity is considered but slow compared with other tissues. The glycosaminoglycan turnover in the disc is quite slow, requiring 500 days.

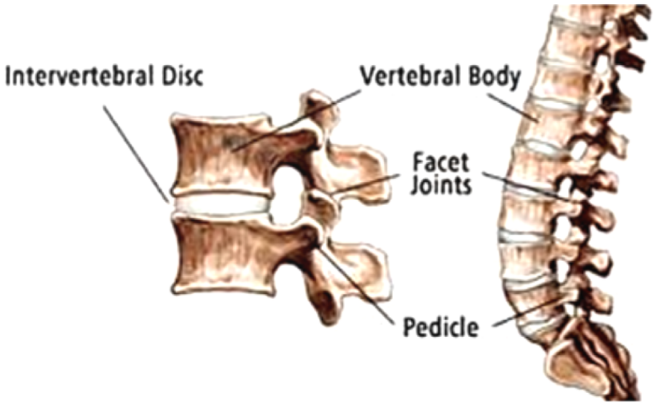


Figure 3: Spinal Motion Segment

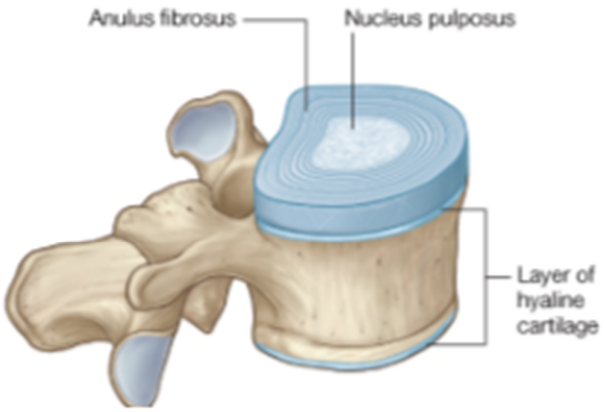


Figure 4:Intervertebral Disc

Farfan H has shown that lumbar disc herniation may be reflective of high stresses at the posterolateral region of the disc secondary to torsion. Also the posterior longitudinal ligament is very weak in the posterolateral aspect. These high loads and weakened posterior longitudinal ligament cause fatigue failure of the annulus fibrosus that enables the inner nucleus pulposus to penetrate the laminations of the annulus gradually until a herniation occurs. Because the region of the disc with the highest torsional stresses is adjacent to the nerve root, these posterolateral herniations nearly always affect the exiting root or the central thecal sac. Less commonly, the disc may protrude into the extraforaminal area and produce compromise of the more proximal exiting root.

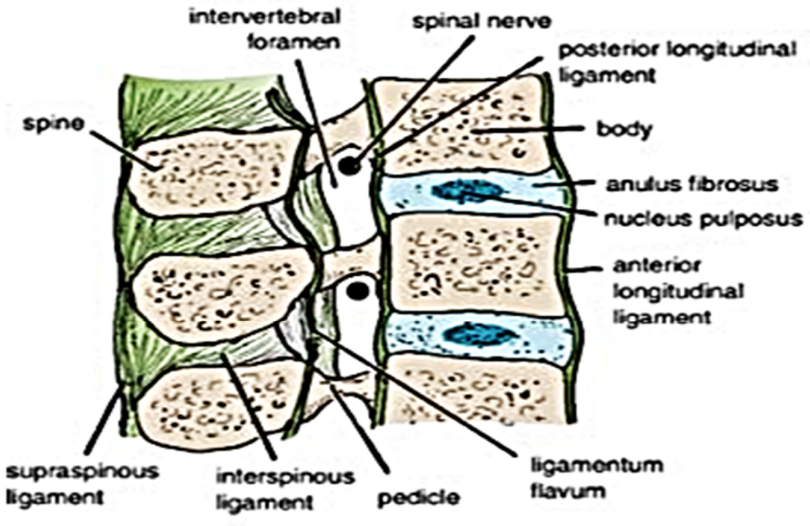


Figure 5: Cross Section Of Lumbo Sacral Spine

BLOOD SUPPLY:

Paired lumbar arteries arise directly from the posterior aspect of the aorta, in front of the bodies of the lumbar vertebrae. During the adult phase of life, there is no active blood supply to the intervertebral discs. The vasculature of the nerve roots is formed by branches from the intermediate branch of the segmental artery distally and by branches from the vasa corona of the spinal cord proximally. The venous supply of the lumbar spine mirrors the arterial supply. The venous system is valveless, draining the internal and external venous system into the inferior vena cava .

NERVE SUPPLY:

The sinuvertebral nerve, arising from its corresponding spinal nerve, innervates the posterior longitudinal ligament, the superficial layer of the annulus fibrosus, the blood vessels of the epidural space, the anterior dura matter, the dural sleeve surrounding the spinal nerve roots and the posterior vertebral periosteum.

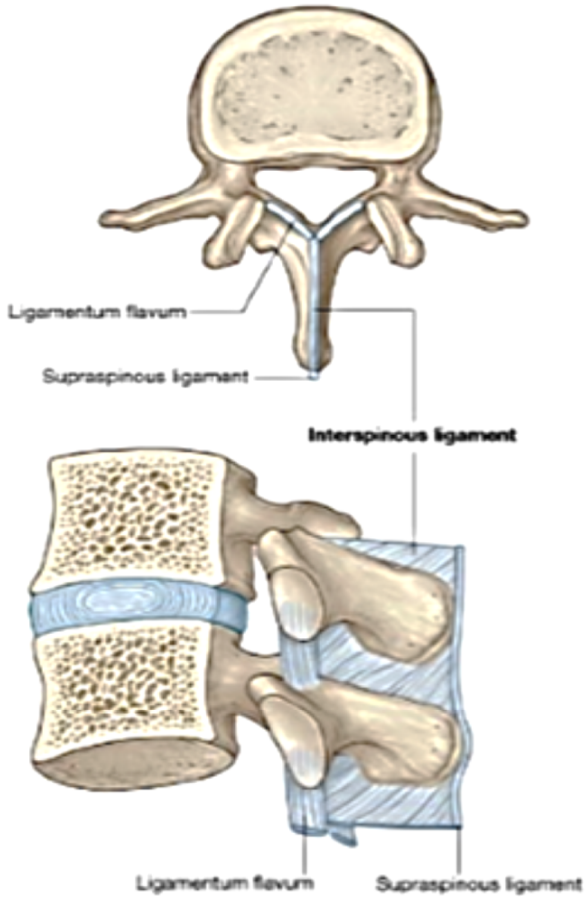


Figure 6: Posterior Elements Of Lumbosacral Spine

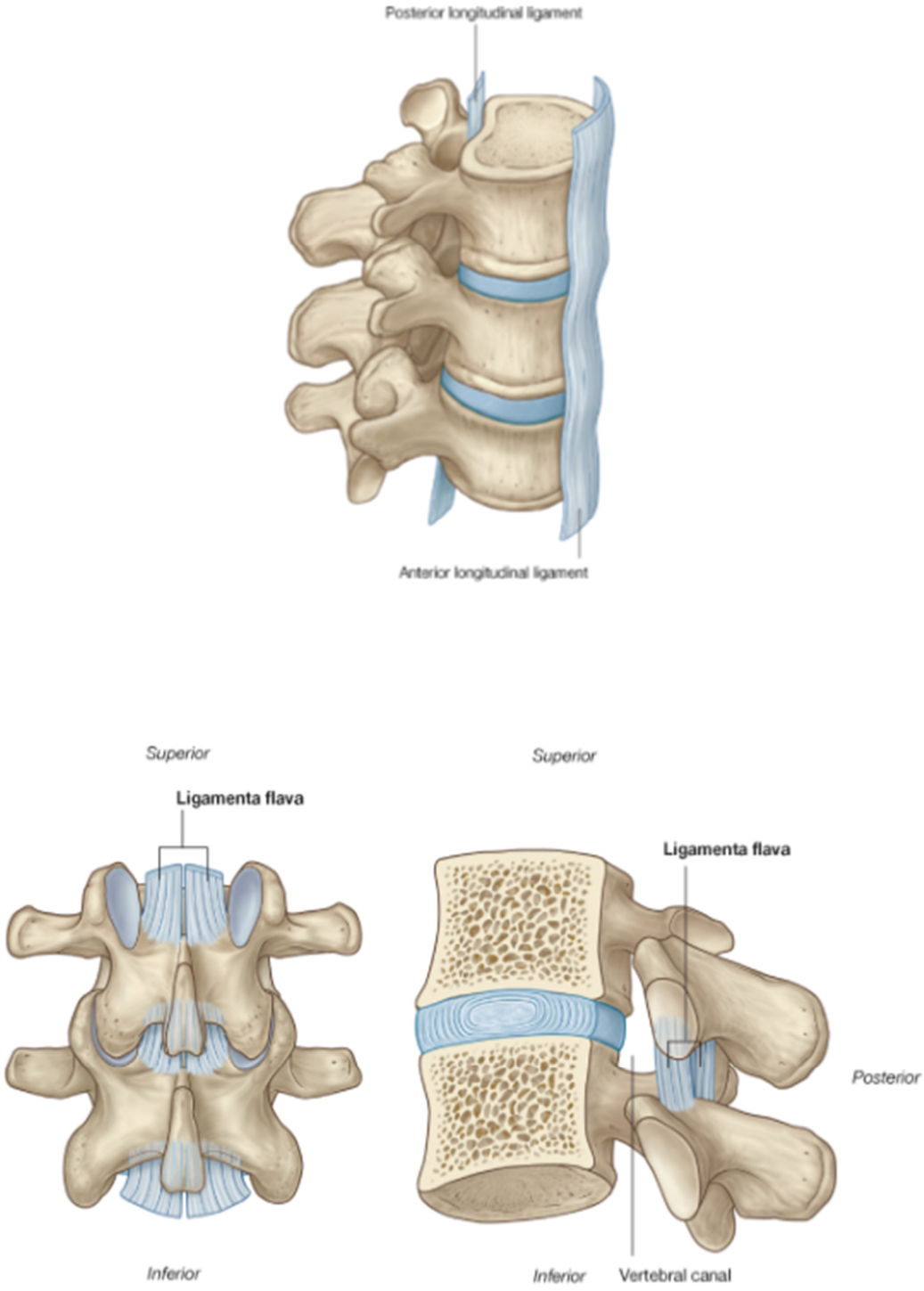


Figure 7:Ligaments Of Lumbo Sacral Spine

LUMBAR DISC DISAESE

One theory of spinal degeneration assumes that all spines degenerate and that current methods of treatment are for symptomatic relief, not for a cure.

The degenerative process has been divided into three separate stages with relatively distinct findings.

The first stage is dysfunction, which is seen in individuals 15 to 45 years old.

It is characterized by circumferential and radial tears in the disc anulus and localized synovitis of the facet joints.

The next stage is instability. This stage, found in 35- to 70-year-old patients, is characterized by internal disruption of the disc, progressive disc resorption, degeneration of the facet joints with capsular laxity, subluxation, and joint erosion.

The final stage, present in patients older than 60 years, is stabilization. In this stage, the progressive development of hypertrophic bone around the disc and facet joints leads to segmental stiffening or frank ankylosis.

Each spinal segment degenerates at a different rate. As one level is in the dysfunction stage, another may be entering the stabilization stage.

Disc herniation in this scheme is considered a complication of disc degeneration in the dysfunction and instability stages.

Spinal stenosis from degenerative arthritis in this scheme is a complication of bony overgrowth compromising neural tissue in the late instability and early stabilization stages.

Long-term follow-up studies of lumbar disc herniations have documented several principles, the foremost being that generally symptomatic lumbar disc herniation (which is only one of the consequences of disc degeneration) has a favorable outcome in most patients.

The primary benefit of surgery has been noted to occur early on in the first year after surgery, but with time the statistical significance of the improvement appears to be lost.

In general, the literature supports an active care approach, minimizing centrally acting medications. **The judicious use of epidural steroids also is supported.**

Non progressive neurological deficits (except cauda equina syndrome) can be treated non operatively with expected improvement clinically.

If surgery is necessary, it usually can be delayed 6 to 12 weeks to allow adequate opportunity for improvement. These principles are consistent with clinical findings and treatment practices at this clinic. Some patients are best treated surgically.

Similar principles are valid regarding cervical disc herniations, which also generally can be treated non operatively. The important exception is a patient with cervical myelopathy, who is best treated surgically.

The natural history of degenerative disc disease is one of recurrent episodes of pain followed by periods of significant or complete relief.

PATHOANATOMY OF INTERVERTEBRAL DISC PROLAPSE:

Weber expressed that, “disc herniation is a collective term, to describe a process with rupture of annulus fibrosus and subsequent displacement of the central mass of the disc into the intervertebral space, common to the dorsal or dorsolateral aspect of the disc. A herniation occurs in a lumbar intervertebral disc when a separate tissue fragment extrudes or sequestrates, through a tear of the annulus. Both a fissure and fragment appears to be required for prolapse to occur.”

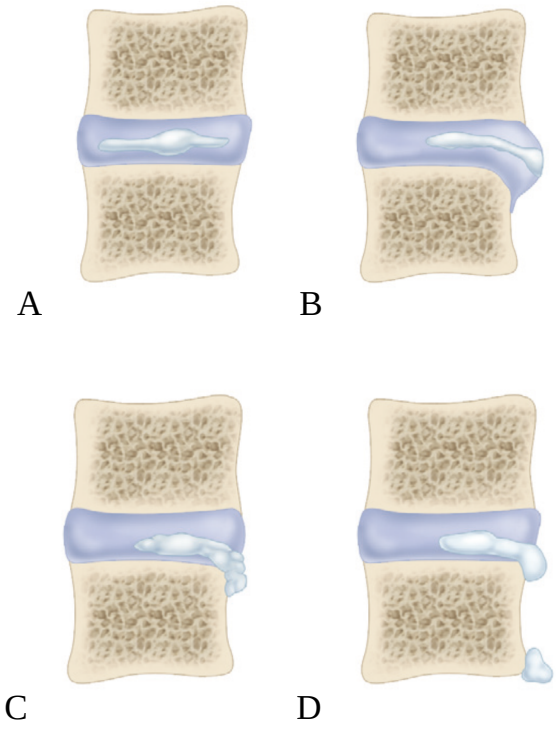


FIG 9; Types of disc herniation.

A, Normal bulge, B. Protrusion, C, Extrusion. D, Sequestration.

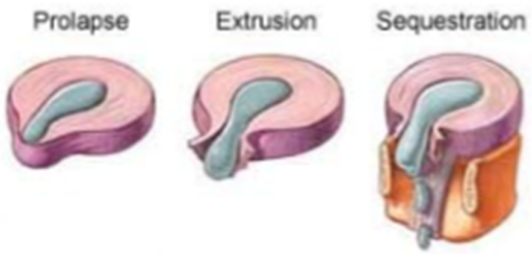


Figure 10: Degree of disc prolapse

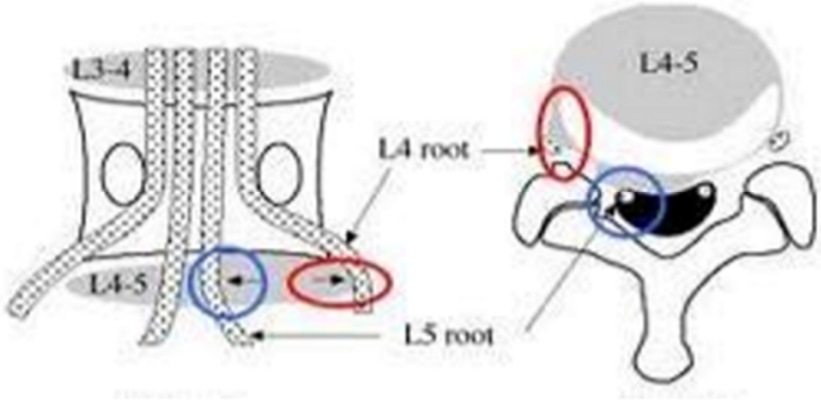


Figure 11 : Location of disc herniation:

Sensory Symptoms:

The sensory symptoms appear with far more frequency than the motor symptoms. The most common symptom, following nerve irritation, is pain, in the form of paraesthesia, hyperesthesia.

Motor Symptoms:

During the initial stage of sciatica, patients are most concerned about sensory dysfunction and may not even notice motor deficits.

Infrequently, the patient may present with lower extremity weakness which may be disabling. This is more likely to occur in disc lesions involving the fourth and fifth lumbar spinal nerve roots.

PHYSICAL EXAMINATION:

O'Connell classified the signs, in lumbar disc herniation as the spinal signs, nerve tension signs and neurological signs.

SPINAL SIGNS:

Loss of normal lumbar lordosis and paravertebral spasm are usually seen during the acute phase of disease. Occasionally in less acute situation the protective muscle spasm may be elicited only when the patient is stressed by prolonged standing or by forward flexion of the spine.

In acute disc prolapse the patient usually will have a list of the spine which has been termed as sciatic scoliosis. When the disc is herniated lateral to the nerve root, the patient will list away from the side of the irritated nerve in an attempt to draw the nerve root away from the disc fragments. When the herniation is medial to the nerve root, the patient may list towards the side of the lesion in an effort to decompress the nerve root. Limitation of spine motion is usually noted during the symptomatic phase of lumbar disc disease, particularly prominent in the

sagittal plane than in the frontal plane. Palpation of the patient either in erect or prone position, may evoke tenderness in the midline, at the level of the disc lesion and in Para vertebral areas on the side of a nuclear extrusion.

NERVE TENSION SIGNS:

Nerve irritation may be elicited by methods which increase the tension on the nerve root.

The straight leg raising test:

The passive straight leg raising test is the most commonly employed one. With the straight leg raising manoeuvre, the L5 and S1 nerve roots, move 2 to 6mm at the level of the foramina. In an analysis of the diagnosis of the straight leg raising test, it was noted that tension is realized within the nerve roots contributing to the sciatic nerve, at 35 to 70 degrees of elevation from the supine position. This test is performed with the patient supine and head flat or on a low pillow. Only when leg pain or reproduction of the patient's radicular pain occurs, the test is considered positive.

Well Leg Raising Test:

Patient lying supine, the unaffected limb is flexed at hip with knee in full extension. If patient develops pain along the sciatic nerve

distribution on the affected side, it is highly suggestive of disc prolapse compressing the exiting nerve root.

Bow String test:

Patient is asked to flex the hip with knee in full extension on the affected side till the pain is felt. At this point, the knee is flexed which instantaneously reduces the pain. On pressing the sciatic nerve in the popliteal fossa the painful radicular symptoms restarts which indicates tension on the nerve roots.

Sciatic nerve stretch test:

Patient is asked to lie supine and the foot is supported and gradually flexed at hip with knee in full extension; during this manoeuvre patient develops pain. When patient develops pain, flexion at hip is stopped, pressure is applied over the anterior aspect of ipsilateral knee in order to extend the knee. If there is sharp radicular pain, it indicates tension on the nerve root.

NEUROLOGIC SIGNS:

A meticulous neurological examination often, but not always, yields objective evidence of nerve root compression. It suggests the level of disc herniation but is not conclusive in this regard. The involved nerve root usually is not completely involved and the neurologic findings may

vary. There may be no objective neurologic findings because the involved nerve often remains functional. Loss of Deep tendon reflex, motor weakness, muscle atrophy or sensory loss will be more suggestive of root compression. The neurological findings in the lumbosacral nerve root lesions are compiled in the following table.

Table 2 : Table showing the Clinical Root Syndrome

Clinical Root Syndrome	Sensory Findings	Motor Findings	Deep tendon Reflex
L4	Numbness over the anteromedial thigh and knee	Weakness and Atrophy of quadriceps.	Knee jerk absent.
L5	Numbness over lateral leg, web of great toe.	Weakness of dorsiflexion of great toe and foot.	Usually none.
S1	Numbness over back of calf, lateral heel, foot and toe.	Weakness of plantar flexion of foot and great toe may be affected.	Ankle jerk diminished or absent.

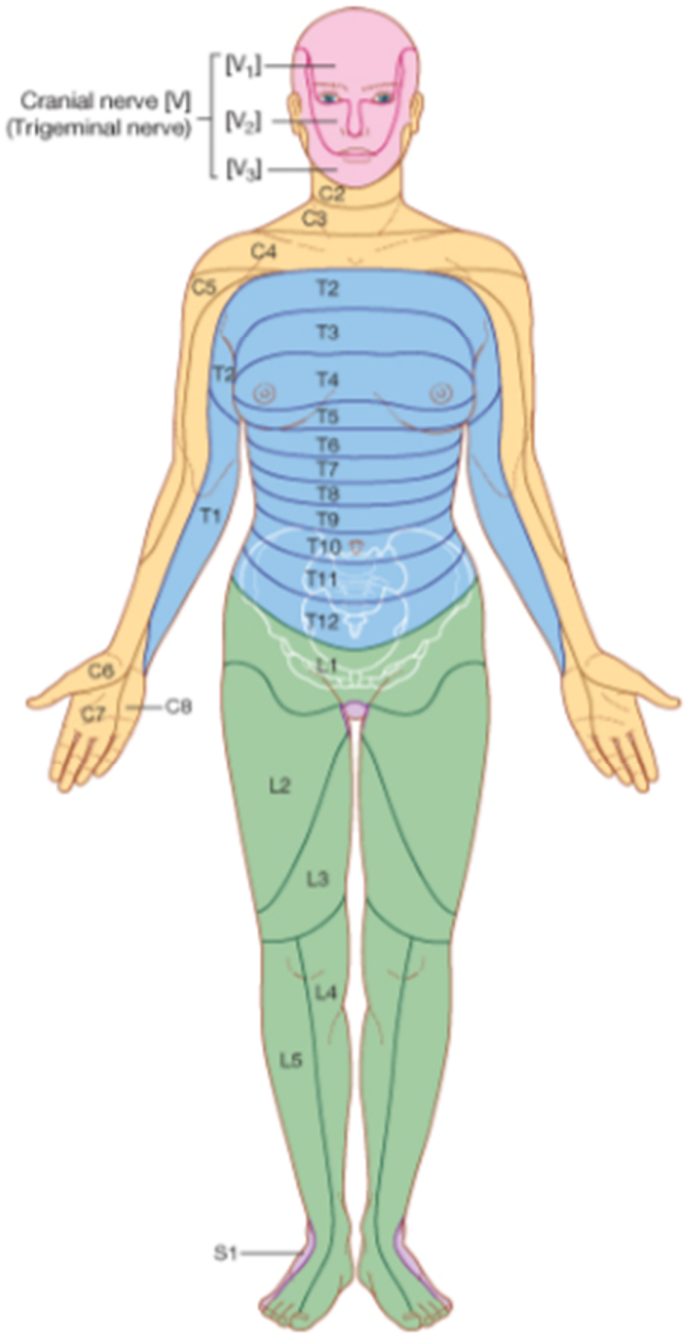


Figure12: Dermatomal Pattern

INVESTIGATIONS

X RAY LUMBO SACRAL SPINE:

The first line of investigations includes X-rays of lumbosacral spine in both anteroposterior and lateral views. There may be loss of lumbar lordosis with scoliosis depending on the location of disc prolapse and uniform reduction of disc space. In acute IVDP there may not be significant reduction in intervertebral disc space. Oblique views and flexion extension views should be taken to rule out instability of spine

MYELOGRAPHY:

In the past, the gold standard in the diagnosis of disc herniation had been the Myelogram. Bell and associates reported the largest series comparing Computed Tomography with Metrizamide Myelography in the diagnosis of surgically proven herniated discs and spinal stenosis. Albeck and associates in a controlled comparison of Myelography, CT and MRI in clinically suspected lumbar disc herniation indicated that CT or MRI should be the first choice of imaging in patients with suspected lumbar disc herniation.

COMPUTED TOMOGRAPHY (CT):

Major advantages of computed tomography over myelography are their ability to visualize the pathology, non-invasiveness and less radiation exposure for patients and radiologists. The importance of correlating, findings in the various imaging modalities with clinical symptoms has been emphasized in several studies. Wiesel and associates performed lumbar CT Scans in 52 asymptomatic subjects. The overall incidence of CT abnormalities was 37% and was more common in persons over 40 years of age.

MAGNETIC RESONANCE IMAGING (MRI):

Magnetic resonance imaging offers increased soft tissue resolution and allow for evaluation of lateral recess pathology, in addition to visualizing the thoraco lumbar region for possible spinal tumours. ModicM.T and co-workers 35 in 1986 investigated the accuracy of MRI, Metrizamide Myelography and CT in lumbar disc disease. Their studies showed that MRI was more accurate than MM (82.3% vs. 71.4%) and was equal to CT (82.3% vs. 83%) in diagnosis of disc herniation. They concluded that the combination of MRI and CT was equal in diagnostic accuracy to the combination of CT and MM (92.5% vs. 89.4%). However, because MRI is non-invasive without any radiation hazard and

has increased soft tissue delineation its advantage to the patient as well as the operating surgeon is obvious.

Boden and colleagues performed lumbosacral MRI scans on 67 asymptomatic subjects. They reported findings suggestive compressive pathology in approximately one third of the subjects studied. These reports emphasize the need for correlation of neuro radiologic findings with clinical symptoms and signs and this is the first step in avoiding surgical complication and failed back surgery syndrome.

Figure 13 A: (Case no: 19) Showing T2 axial L5-S1 Right Para median herniation compressing Right S1 nerve root

Figure 13 B: (Case no: 19) Showing T2 sagittal L5-S1 herniation

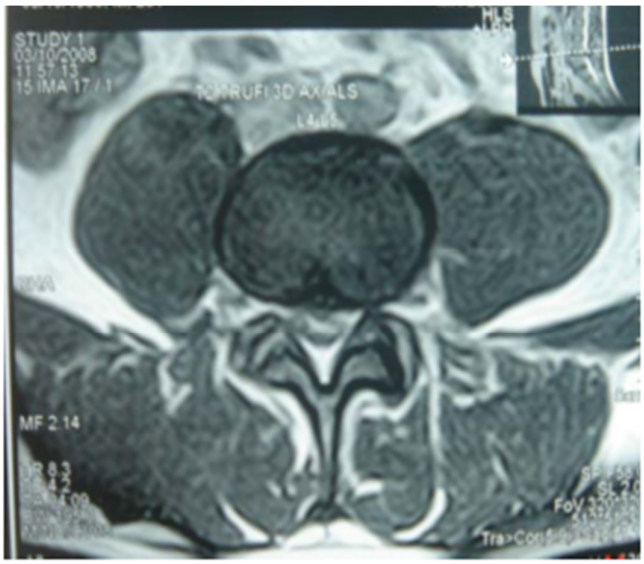


Figure 14 A : (Case no: 13) Showing T2 axial L4 -L5 left Para median protrusion compressing left L5 nerve root

Figure 14 B : (Case no: 13) Showing T2 sagittal L4-L5 protrusion indenting on thecal sac

MANAGEMENT

1. **NONOPERATIVE TREATMENT**
2. **OPERATIVE TREATMENT**

1) NONOPERATIVE TREATMENT

I. CONSERVATIVE TREATMENT:

Currently variety of non-operative therapies for back and leg pain are available. They are are simple rest, massage, heat therapy, traction therapy. These sort of therapies are reported as producing " miraculous cures". But adequate scientific proof for these sort of therapies are very few.

Patients with early lumbar disc herniation benefit from conservative treatment. Patients with a definite diagnosis of ruptured lumbar intervertebral disc and sciatica, with neurological signs and symptoms should be carefully observed can be treated by non-surgical means for a period of 4-8 weeks, unless there is progressive loss of motor, sensory bladder or bowel function before the diagnosis. "Weber, Holme and Amlie reported that 70% of patients with sciatica had a considerable reduction in pain within four weeks". The conservative treatment of lumbar disc herniation consists of bed rest and traction, medications, physiotherapy.

A. BED REST AND TRACTION:

The simplest treatment for acute back pain is rest. Pain relief is usually experienced by a patient confined to bed. The optimal position is supine with knees and hips flexed.

B. MEDICATIONS:

Drug therapy may be directed to reduce nerve root inflammation, pain and for muscle relaxation. The sciatic pain is due to a perineural inflammatory response to the herniated disc material. In many instances this inflammatory change is decreased by anti-inflammatory drugs. Bed rest remains the best way to treat muscle spasm. Anti-depressants reduce the need for analgesics in patients with chronic pain.

C.PHYSIOTHERAPY:

Several physical agents are used for the therapeutic management of low back pain, out of these the most important are Short Wave Diathermy(SWD), Interferential Therapy (IFT), and Transcutaneous Electric Nerve Stimulation (TENS) . SWD are high frequency current commonly used at 27.12 MHz. It generates deep heat without any discomfort and increases local blood flow, thereby washes away the metabolic end products and brings about resolution of inflammation.

IFT is a method of producing low frequency alternating currents around 4000 Hertz. Direct stimulation by interference current produces inhibition of sympathetic system resulting in vasodilatation and helps in removal of pain metabolites and exudates if present. It also reduces pain based on “gate theory of Melzack and Wall.”

TENS is the application of pulsed rectangular wave current forms through surface electrodes on the skin. It works on the principle of the pain gate theory and achieves pain relief by stimulating large afferent fibres preferentially, thus inhibiting transmission of pain impulses.

II. EPIDURAL STEROID INFILTRATION :

The epidural injection of a combination of a long acting steroid with an epidural anaesthetic is directed to reduce the inflammatory component of disc herniation. 60-70 percent of satisfactory results have been described in literature. Low pressure headaches, sciatic pain reproduced during injection and a transitory motor weakness lasting 15-20 minutes are some of the associated complications.

III. SURGICAL MANAGEMENT:

When conservative treatment fails for lumbar disc herniation, the next consideration is surgical treatment and the options are as follows.

1. Chemonucleolysis
2. Standard laminectomy and discectomy
3. Microscope assisted lumbar discectomy
4. Percutaneous Discectomy
5. Discectomy and Spinal Fusion
6. Total Disc Replacement

INJECTION STUDIES

Whenever a diagnosis is in doubt, and the complaints seem real or the pathological condition is diffuse, identification of the source of pain is problematic. The use of local anesthetics or contrast media in various specific anatomical areas can be helpful. These agents are relatively simple, safe, and minimally painful.

Contrast media such as diatrizoate meglumine (Hypaque), iothalamate Meglumine (Conray), iopamidol, Iohexol (Omnipaque), and metrizamide (Amipaque) have been used for discography and nerve blocks with no reported ill effects. Reports of neurological complications with contrast media used for discography and subsequent chymopapain injection are well documented.

The best choice of a contrast medium for documenting structures outside the subarachnoid space is an absorbable medium with low reactivity because it might be injected inadvertently into the subarachnoid space. Iohexol and metrizamide are the least reactive, most widely accepted, and best tolerated of the currently available contrast media.

Local anesthetics, such as lignocaine (Xylocaine), tetracaine and bupivacaine are used frequently epidurally and intradurally.

The use of bupivacaine should be limited to low concentrations and low volumes because of reports of death after epidural anesthesia using concentrations of 0.75% or higher.

Steroids prepared for intramuscular injection also have been used frequently in the epidural space with few and usually transient complications. Spinal arachnoiditis in past years was associated with the use of epidural methylprednisolone acetate (Depo-Medrol). This complication was thought to be caused by the use of the suspending agent, polyethylene glycol, which has since been eliminated from the Depo-Medrol preparation. For epidural injections, betamethasone provides immediate and long term duration of action. It is highly soluble, and contains no harmful preservatives. other commonly used preparations for spinal injections include methylprednisolone (Depo-Medrol) and

triamcinolone . Isotonic saline is the only other injectable medium used frequently around the spine with no reported adverse reactions.

EPIDURAL CORTISONE INJECTIONS

Epidural injections in the cervical, thoracic, and lumbosacral spine were developed to diagnose and treat spinal pain.

Information obtained from epidural injections (ESI) can be helpful in confirming pain generators that are responsible for a patient's discomfort. Structural abnormalities do not always cause pain, and diagnostic injections can help to correlate abnormalities seen on imaging studies with associated pain complaints.

In addition, epidural injections can provide pain relief during the recovery phase of disc or nerve root injuries and allow patients to increase their level of physical activity. Because severe pain from an acute disc injury with or without radiculopathy often is time limited, therapeutic injections help to manage pain and may alleviate or decrease the need for oral analgesics

LUMBAR EPIDURAL INJECTION

Certain clinical trends are apparent with lumbar epidural steroid injections. When nerve root injury is associated with a disc herniation

or lateral bony stenosis, most patients who received substantial relief of leg pain from a well-placed transforaminal injection, even if temporary, benefit from surgery for the radicular pain.

Table 3 Common Corticosteroids Used in Spinal Interventions Compared with Hydrocortisone

	HYDRO CORTISONE	METHYL PREDNISOLE (DEPOMEDROL)	TRIAMCINOLONE	BETAMETHASONE
Relative Anti-inflammatory potency	1	5	5	25
pH	5.0-7.0	7-8	4.5-6.5	6.8-7.2
Onset	Fast	Slow	Moderate	Fast
Duration of action	Short	Intermediate	Intermediate	Long
Concentration (mg/mL)	50	40-80	20	6
Relative mineralocorticoid activity	2+	0	0	0

Patients who do not respond and who have had radicular pain for at least 12 months are unlikely to benefit from surgery. Patients with back

and leg pain of an acute nature (<3 months) respond better to epidural corticosteroids.

Unless a significant re-injury results in an acute disc or nerve root injury, postsurgical patients tend to respond poorly to epidural corticosteroids.

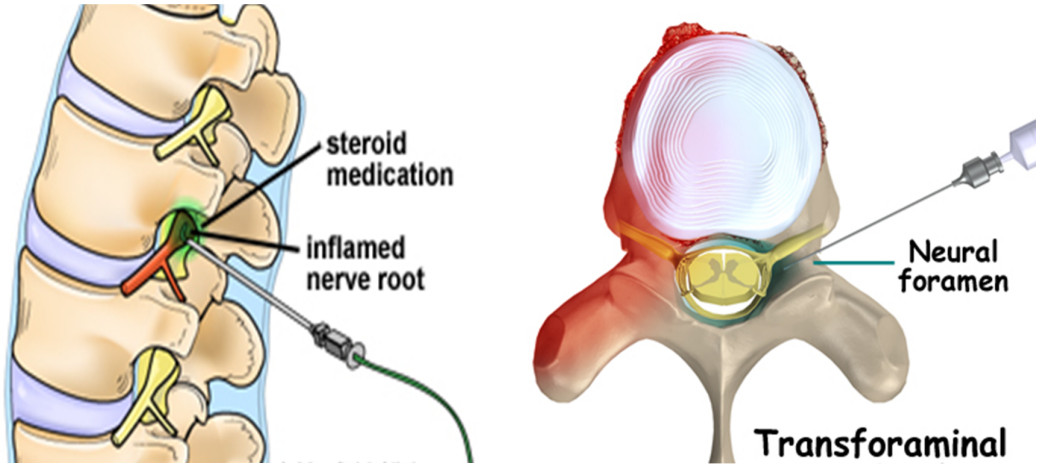


Figure 15A : Transforaminal Approach

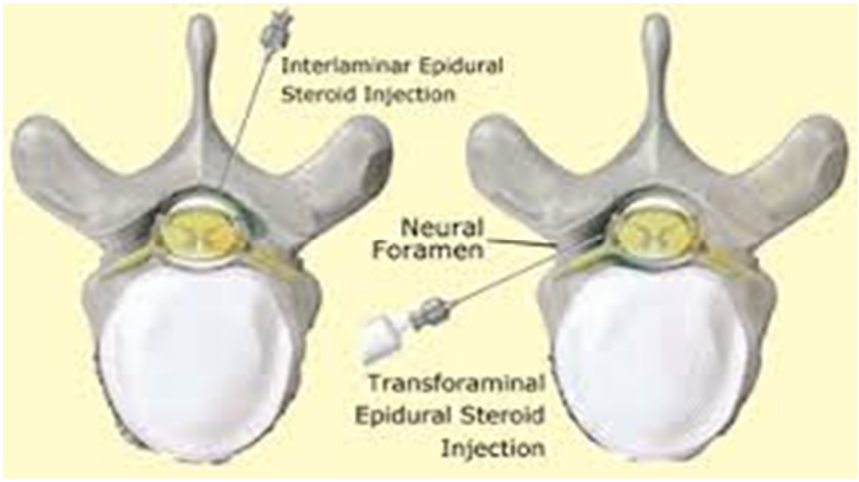


Figure 15B : Transforaminal & Interlaminar Approach

Materials & Methods

MATERIALS AND METHODS

This study was conducted at Rajiv Gandhi Government General Hospital Chennai from March 2014 to Sep 2015.

One hundred patients with back pain documented with lumbar disc disease treated initially with rest, analgesics and physiotherapy for at least six weeks were included in the study and were treated with epidural steroid injection. The protocol was approved by ethical committee.

Patients to participate in this study were documented. Patients with lumbar disc disease were given transforaminal epidural or intralaminar epidural steroid injection since 1/3/2014 in Ortho OT of our institute & Pain clinic OT.

INCLUSION CRITERIA

1. Patients with duration of back pain and radiculopathy for more than 6 months with radiological evidence (MRI & X- RAY) of lumbar disc disease.
2. MRI scan showing an herniated nucleosus pulposus (HNP) of intervertebral disc with less than 50% intervertebral canal narrowing with manifestations of backache and radiculopathy.

HNPs at various interspaces (L3–L4, L4–L5, L5–S1) and with differing axial presentations (*e.g.*, far lateral, paracentral, and central protrusion) were examined.

3. Age group between 18 to 65 years.

.

EXCLUSION CRITERIA

1) Patients with more than 2 level lumbar disc disease.
2) Patients with progressive neurological deficits.
3) Patients who underwent prior lumbar surgery.
4) Patients with a large herniation with severe central or foraminal stenosis on MRI,
5) Coagulation disorder.
6) Patients with a history of anaphylaxis to local anesthetics or corticosteroid.

Patients who met inclusion criteria were obtained informed consent after explaining all risks, benefits, objectives and outcomes of the study. They were all explained about nature of study.

Two groups were assigned

GROUP 1- TRANSFORAMINAL EPIDURAL STEROID (TFESI)

GROUP 2- INTERLAMINAR EPIDURAL STEROID (ILESI)

Each group con tains 50 patients. Pt having predominant unilateral symptoms were given transforaminal steroids. Other patients on random basis were equally divided. These patients were followed for one year. No patients were missed.

The following methods were used to apply the epidural steroid.

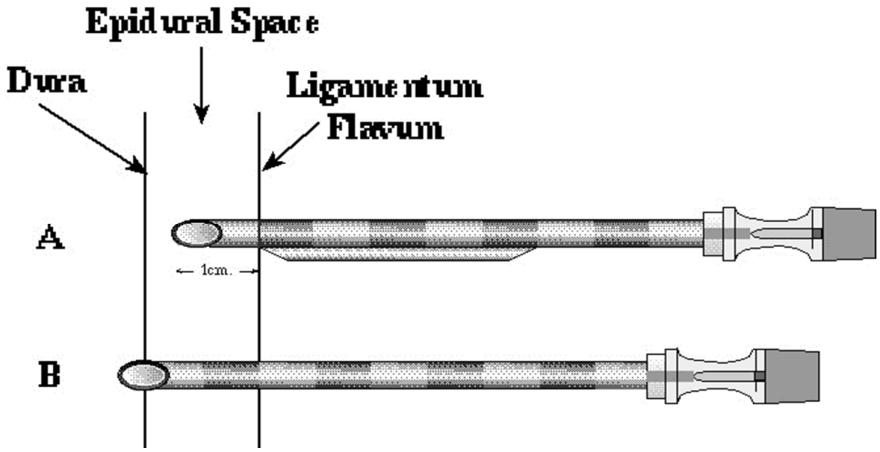


Figure 16A : Tuohy epidural needle

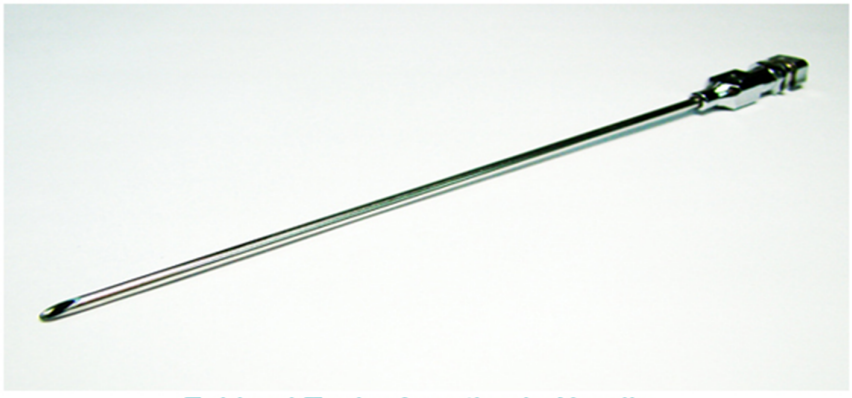


Figure 16B : Tuohy epidural needle

TRANSFORAMINAL LUMBAR EPIDURAL INJECTION

- Place the patient prone on a fluoroscopy compatible surgical table. Under sterile aseptic precautions, the parts (fig 17) above and below the interspace to be injected were prepared and draped.
- A 22-gauge, 4 ¾ inch spinal needle is then inserted and advanced within the anesthetized soft tissue track under fluoroscopy guidance until contact is made near the junction of the superior articular process and lower edge of the superior transverse process.
- The spinal needle is retracted 2 to 3 mm, redirected towards the base of the appropriate pedicle and advanced it slowly to the 6-o'clock position of the pedicle under fluoroscopy. Adjusted the C-arm to a lateral projection to confirm the position, and then returned the C-arm to the anteroposterior view.
- Confirmed placement in safe triangle. Safe triangle roof is formed by pedicle, exiting nerve root forms tangential base and vertebral body forms lateral border.
- S1 was accessed with 22 gauge 3.5-inch spinal needle. Needle placed under fluoroscopic guidance in upper outer quadrant of ipsilateral S1 foramen.

- The stylet was removed and 1 mL of iohexol nonionic contrast agent was injected slowly to produce a perineurosheathogram observed adequate dye pattern.

At each level of nerve root, one ml of iohexol nonionic contrast agent was injected after positioning under C-ARM guidance. Needle position re-adjusted if fluoroscopy didn't reveal flow to ipsilateral nerve root.

After documenting adequate flow of contrast to target site and no blood or cerebrospinal fluid was aspirated, 2ml of triamicinolone (each ml containing 40 mg) with 1ml of preservative free lignocaine were given. Injection were never given more than 2 levels to avoid systemic side effects of steroid.

The patients in Group I with the total of 50 patients (with average age of 47.1, with second dose of steroid in 21 poor responders after 4 weeks apart, total 72 injections of TFESI) received an average of 1.42 TFESI were followed for 12 months.

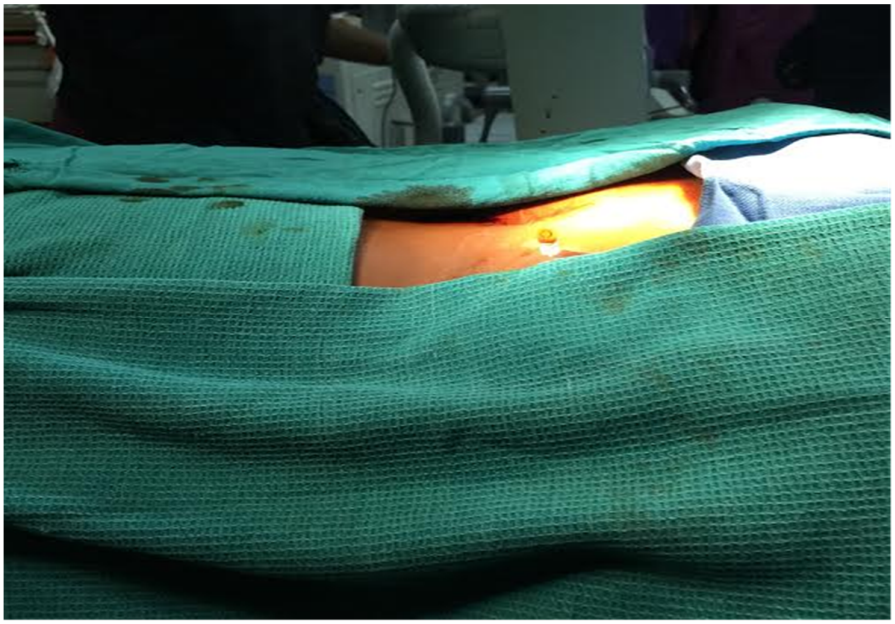


Figure 17A : Aseptic Prepartion

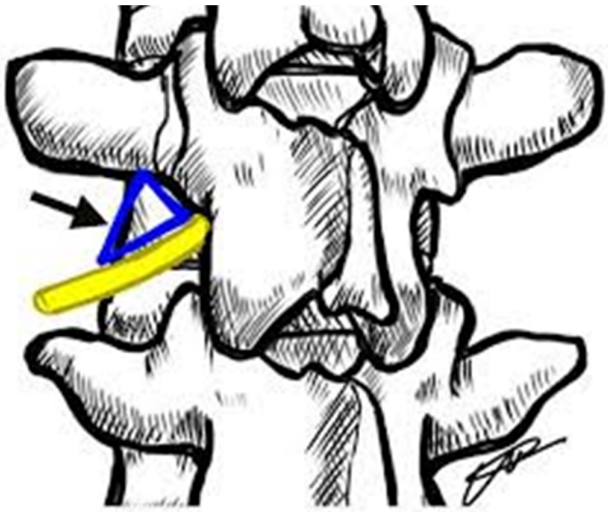


Figure 17B : Safe Triangle

Figure 18 : Injecting Contrast

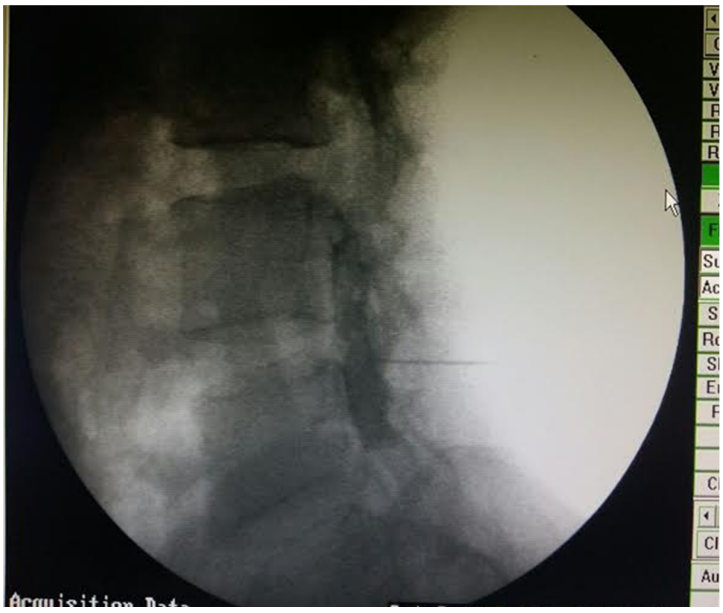


Figure 19 : Establishing Contrast Pattern

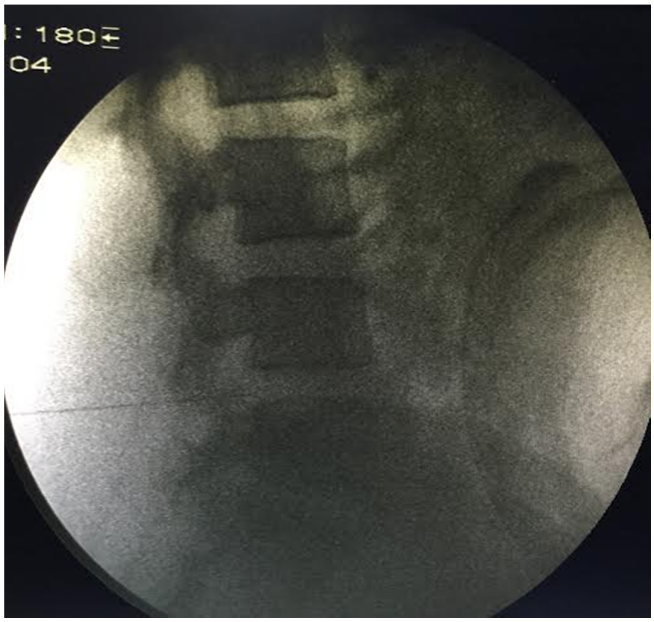


Figure 20 : Lateral view of LS spine showing needle in position

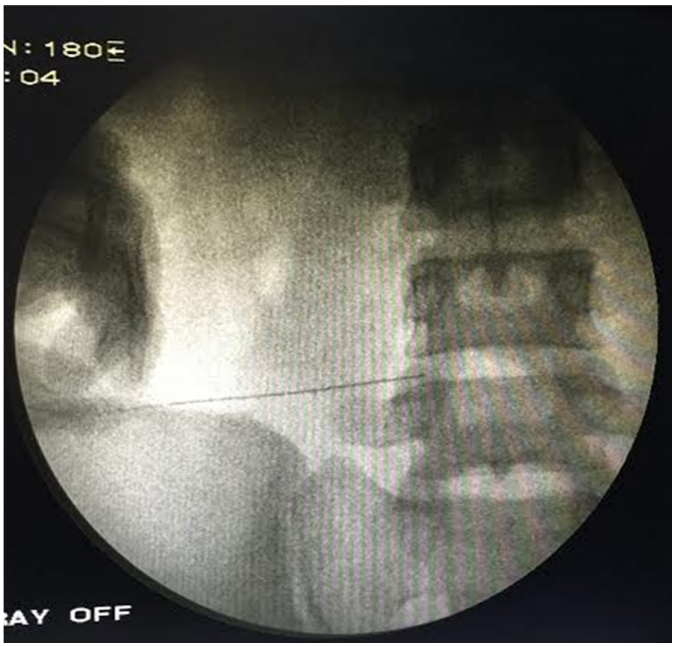


Figure 21: AP view of LS spine showing needle in position

Figure 22 : Injecting Transforaminal Epidural Steroid

INTERLAMINAR LUMBAR EPIDURAL INJECTION

Patient prone position on a fluoroscopy compatible surgical table. Aseptically prepared the part with isopropyl alcohol and povidone-iodine several segments above and below the laminar interspace to be injected. Draped the part in a sterile fashion.

Under anteroposterior fluoroscopy view, identified the target interlaminar space. Using a 27-gauge, ¼ -inch needle, anesthetized the part over the target interspace on the side of the patient's symptom with 1 mL of 1% preservative-free lignocaine without epinephrine.

22-gauge, $3^{1/2}$ -inch spinal needle inserted vertically until contact is made with the upper edge of the inferior lamina at the target interspace, 1 to 2 cm lateral to the caudal tip of the inferior spinous process under fluoroscopy. Anesthetized the lamina with 1-2 mL of 1% preservative-free lidocaine without epinephrine. Anesthetized the soft tissue with 2 mL of 1% lidocaine as the spinal needle is withdrawn.

Nicked the skin with an 18-gauge hypodermic needle, and inserted a 17-gauge, $3^{1/2}$ -inch Tuohy epidural needle. Advanced it within the soft tissue track vertically until contact made with the lamina under fluoroscopic image guidance.

"Walk off" the lamina with the Tuohy needle onto the ligamentum flavum. Removed the stylet from the Tuohy needle, and attached a 10-mL syringe filled halfway with air and sterile saline to the Tuohy needle. Advanced the Tuohy needle into the epidural space using the loss-of-resistance technique. Avoided lateral needle placement to decrease the likelihood of encountering an epidural vein or adjacent nerve root. Removed the stylet when loss of resistance has been achieved. Aspirated to check for blood or CSF. If neither blood nor CSF is present, removed the syringe from the Tuohy needle and attached a 5-mL syringe containing 2 mL of nonionic contrast dye.

Epidural placement confirmed by an epidurogram with the iohexol. Placement documented with flouroscopy.

Removed the 5-mL syringe, and placed on the Tuohy needle. 10-mL syringe containing 1 mL of 1% preservative-free lidocaine and 2 mL of 40 mg/mL triamicinolone.

Inject the corticosteroid preparation slowly into the epidural space. Group II total 50 patients with an average age 45.2 had 30 poor responders. They were given second dose 4 weeks later. ILESI Group received an average of 1.6 ESIs (total of 80) and were followed for 12 months.

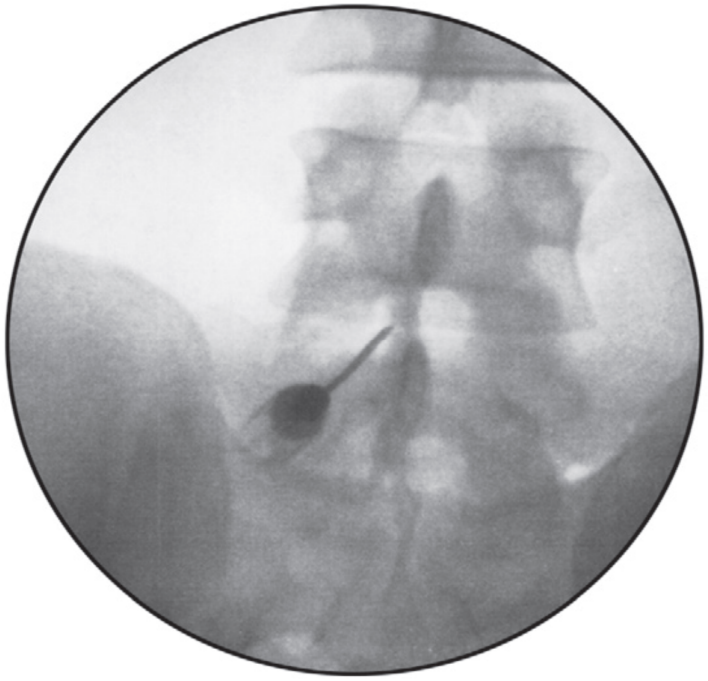


Figure 23A : Posteroanterior view of lumbar interlaminar epidurogram showing characteristic contrast flow pattern

Figure 23 B : Lateral radiograph of lumbar epidurogram.

Self-directed lumbar stabilization programme were given for both groups. It consisted of

1) Abdominal strengthening exercises
2) Lumbar paraspinal strengthening
3) Hip flexibility
4) Hamstring flexibility

Started immediately after injection in both study groups.

Assessment and Follow-up

Compliance was ensured by therapeutic exercises reinforcement during follow-up visits.

Outcome of treatment was measured by

1) **PATIENT SATISFACTION SCALE.**

   It had choice options as

   0 (poor)

   1 (fair)

   2 (good)

   3 (very good)

   and 4 (excellent).

2) **ROLAND MORRIS LOW BACK PAIN DISABILITY QUESTIONNAIRE (RMDQ)** showing improvement by an increase in score;

3) Measurement of **FINGER-TO FLOOR DISTANCE**. It is done with the patient in fully tolerated hip flexion;
4) **VISUAL NUMERIC PAIN SCALE** similar to the visual analog scale with a range of options from 0 (no pain) to 10 (worst pain).

Outcome measures were assessed as follows:

1) Before and after treatment, then at 2 weeks, 1month, 3 month, 6 months and 12 months by a staff nurse blinded to programme.
2) Pt advised not to use Narcotics or NSAID medication during study period. During follow up, patients were assessed for neurologic detoriation, worsening of pain, also new development of pain. Patients who failed to respond were given additional one dose of injection through same approach. Time interval between 2 doses were minimum of one month.

A **successful outcome** defined as

- improvement of a patient satisfaction score of 2 (good) or 3 (very good), 4 (excellent). (Improvement of at least 2 scores)

- improvement on the Roland-Morris Disability score of 5 or more,
- and pain reduction greater than 50% (with visual numeric scale of 1,2,3) at least 3 months after treatment.

The Roland-Morris Low Back Pain and Disability Questionnaire

I stay at home most of the time because of my back.

I change position frequently to try to get my back comfortable.

I walk more slowly than usual because of my back.

Because of my back, I am not doing any jobs that I usually do around the house.

Because of my back, I use a handrail to get upstairs.

Because of my back, I lie down to rest more often.

Because of my back, I have to hold on to something to get out of an easy chair.

Because of my back, I try to get other people to do things for me.

I get dressed more slowly than usual because of my back.

I only stand up for short periods of time because of my back.

Because of my back, I try not to bend or kneel down.

I find it difficult to get out of a chair because of my back.

My back is painful almost all of the time.

I find it difficult to turn over in bed because of my back.

My appetite is not very good because of my back.

I have trouble putting on my sock because of the pain in my back.

I can only walk short distances because of my back pain.

I sleep less well because of my back.

Because of my back pain, I get dressed with the help of someone else.

I sit down for most of the day because of my back.

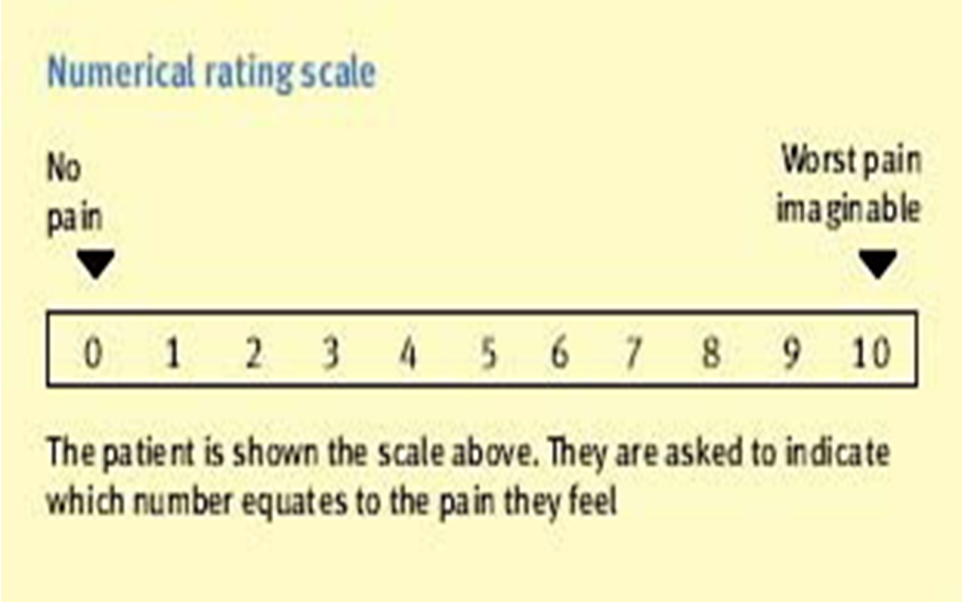
I avoid heavy jobs around the house because of my back.

Because of back pain, I am more irritable and bad tempered with people than usual.

Because of my back, I go upstairs more slowly than usual.

I stay in bed most of the time because of my back.

VISUAL NUMERIC RATING SCALE



RESULTS

In TFESI group, 36 patients out of 50 showed improvements at the end of one year where as in ILESI group, only 28 showed significant improvements at the end of year as per Patient Satisfaction Score study.

In TFESI Group, 8 patients didn't show any improvement (6 patients absent response, 2 patients negligible improvement, among them 2 were females)

In ILESI Group, 20 patients didn't show any improvement (13 patients absent response, 7 patients negligible improvement, among them 11 were females).

Complications, such as dural puncture, excessive bleeding or infection were not reported in both groups. But headache was reported in 2 patients in ILESI.

Table 4- Frequency table for sex in each sub cohort

TREATMENT TYPE		Frequency	Percent	Valid Percent	Cumulative Percent
TFESI	Female	16	32.0	32.0	32.0
	Male	34	68.0	68.0	100.0
	Total	50	100.0	100.0	
ILESI	Female	19	38.0	38.0	38.0
	Male	31	62.0	62.0	100.0
	Total	50	100.0	100.0	

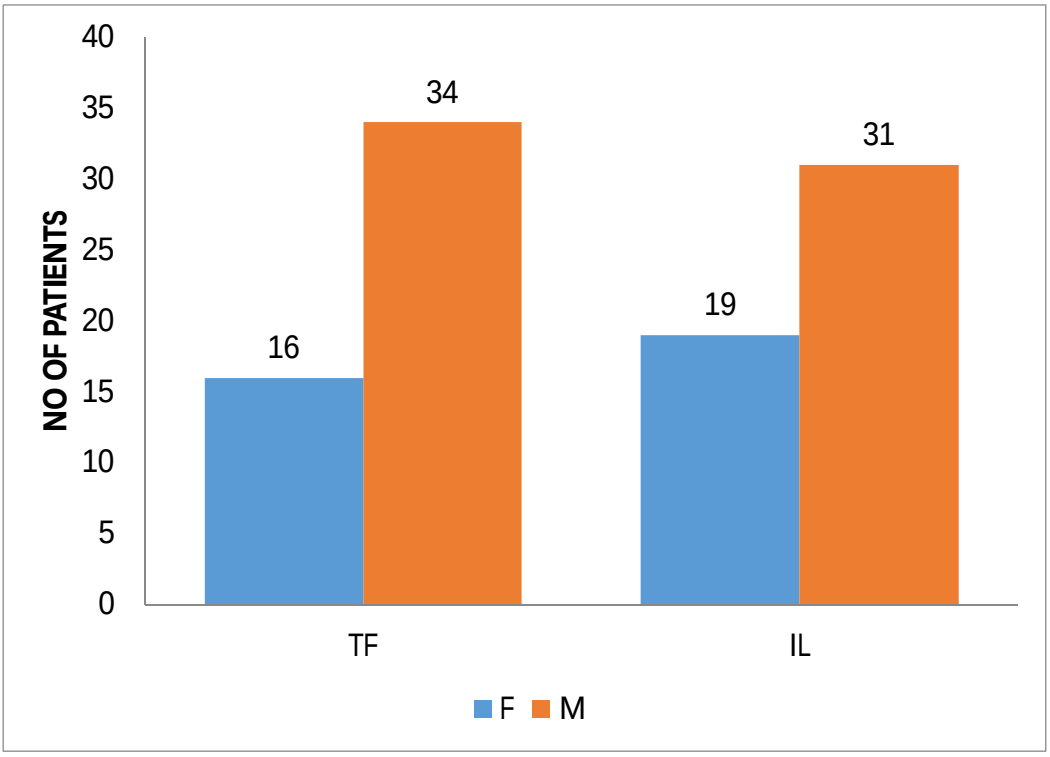


Chart Showing Sex Distribution.

Female (Blue Colour) And Male (Orange Colour)

Table 5A. Descriptives- Mean and Standard deviation in TFESI group.

Descriptive Statistics						
TREATMENT TYPE		N	Minimum	Maximum	Mean	Std. Deviation
TRANSFORAMINAL EPIDURAL GROUP	Roland@pre treatment	50	12	20	16.52	2.002
	Roland@1month	50	6	17	11.04*	2.579
	Roland@3month	50	6	17	11.70	2.558
	Roland@6month	50	7	18	12.30	2.636
	Roland@12month	50	7	19	13.14	2.828
	Finger@Pre treatment	50	40	80	63.16	8.505
	Finger@1month	50	15	69	32.52*	14.336
	Finger@3month	50	16	69	34.94*	14.596
	Finger@6month	50	18	75	37.14*	15.931
	Finger@12month	50	19	75	40.18	16.768
	Satisfication@Pre treatment	50	0	1	.26	.443
	Satisfication@1month	50	0	4	2.96*	1.195
	Satisfication@3month	50	1	4	2.70*	1.147
	Satisfication@6month	50	0	4	2.54*	1.199
	Satisfication@12month	50	0	4	2.26*	1.175
	Visual@Pre treatment	50	7	9	8.58	.538
	Visual@0	50	1	8	3.30*	2.197
	Visual@15th day	50	1	8	3.74*	2.284
	Visual@1month	50	1	9	4.02*	2.369
	Visual@3month	50	1	9	4.06*	2.469
	Visual@6month	50	1	9	4.32*	2.543
	Visual@1y	50	2	9	4.58	2.635

*means study showing successful results. *In RMDQ mean reduction of disability by 5 scores. *In finger floor distance analysis 25 cm increase in finger floor distance analysis. In patient satisfaction score by mean improvement of 2 scores. *In visual numeric scale by mean reduction of 50 percent of pain scores. Visual 0 - means on day of treatment.

*** Table 5B. Descriptives Mean and Standard deviation in ILESI group.**

TREATMENT TYPE		N	Minimum	Maximum	Mean	Std. Deviation
INTERLAMINAR EPIDURAL STEROID GROUP	Roland@Pre treatment	50	13	19	16.38	1.413
	Roland@1month	50	10	16	13.38	1.817
	Roland@3month	50	10	17	13.50	1.876
	Roland@6month	50	10	17	13.58	1.939
	Roland@12month	50	10	19	13.84	2.064
	Finger@Pre treatment	50	50	70	63.84	5.250
	Finger@1month	50	23	69	44.62	14.168
	Finger@3month	50	23	69	45.18	14.512
	Finger@6month	50	23	69	45.64	14.602
	Finger@12month	50	23	69	46.16	14.829
	Satisfication@Pretreatment	50	0	1	.02	.141
	Satisfication@1month	50	0	4	1.94	1.316
	Satisfication@3month	50	0	4	1.78	1.282
	Satisfication@6month	50	0	4	1.76	1.287
	Satisfication@12month	50	0	4	1.70	1.282
	Visual@Pre treatment	50	8	9	8.84	.370
	Visual@0	50	2	9	4.70	2.605
	Visual@15th day	50	2	9	4.92	2.747
	Visual@1month	50	2	9	5.06	2.810
	Visual@3month	50	2	9	5.10	2.852
	Visual@6month	50	2	9	5.20	2.814
	Visual@1year	50	2	9	5.30	2.757

Visual 0 - means on day of treatment

Table 6. Descriptives p value study

	Treatment	N	Mean	SD	P value
Roland@Pre treatment	TFESI	50	16.52	2.002	0.687
	ILESI	50	16.38	1.413	
Roland@1month	TFESI	50	11.04	2.579	*<0.001**
	ILESI	50	13.38	1.817	
Roland@3month	TFESI	50	11.70	2.558	*<0.001**
	ILESI	50	13.50	1.876	
Roland@6month	TFESI	50	12.30	2.636	*0.007**
	ILESI	50	13.58	1.939	
Roland@12month	TFESI	50	13.14	2.828	0.161
	ILESI	50	13.84	2.064	
Finger@Pre treatment	TFESI	50	63.16	8.505	0.632
	ILESI	50	63.84	5.250	
Finger@1month	TFESI	50	32.52	14.336	*<0.001
	ILESI	50	44.62	14.168	
Finger@3month	TFESI	50	34.94	14.596	*<0.001
	ILESI	50	45.18	14.512	
Finger@6month	TFESI	50	37.14	15.931	*0.006
	ILESI	50	45.64	14.602	
Finger@12month	TFESI	50	40.18	16.768	.062
	ILESI	50	46.16	14.829	
Satisfication@Pre treatment	TFESI	50	.26	.443	<0.001
	ILESI	50	.02	.141	
Satisfication@1month	TFESI	50	2.96	1.195	*<0.001
	ILESI	50	1.94	1.316	
Satisfication@3month	TFESI	50	2.70	1.147	*<0.001
	ILESI	50	1.78	1.282	
Satisfication@6month	TFESI	50	2.54	1.199	*0.002
	ILESI	50	1.76	1.287	
Satisfication@12month	TFESI	50	2.26	1.175	*0.025
	ILESI	50	1.70	1.282	

Visual@Pre treatment	TFESI	50	8.58	.538	*0.006
	ILESI	50	8.84	.370	
Visual@0	TFESI	50	3.30	2.197	*0.005
	ILESI	50	4.70	2.605	
Visual@15days	TFESI	50	3.74	2.284	*0.022
	ILESI	50	4.92	2.747	
Visual@1month	TFESI	50	4.02	2.369	*0.048
	ILESI	50	5.06	2.810	
Visual@3month	TFESI	50	4.06	2.469	0.054
	ILESI	50	5.10	2.852	
Visual@6month	TFESI	50	4.32	2.543	0.104
	ILESI	50	5.20	2.814	
Visual@1year	TFESI	50	4.58	2.635	0.185
	ILESI	50	5.30	2.757	

*means study significant with p value of <0.05

Table 7- T-Test study of standard error of mean.

Group Statistics					
	Treatment type	N	Mean	Std. Deviation	Std. Error Mean
Roland @Pre treatment	TFESI	50	16.52	2.002	.283
	ILESI	50	16.38	1.413	.200
Roland@1month	TFESI	50	11.04	2.579	.365
	ILESI	50	13.38	1.817	.257
Roland@3month	TFESI	50	11.70	2.558	.362
	ILESI	50	13.50	1.876	.265
Roland@6month	TFESI	50	12.30	2.636	.373
	ILESI	50	13.58	1.939	.274
Roland@12month	TFESI	50	13.14	2.828	.400
	ILESI	50	13.84	2.064	.292

Finger @Pre treatment	TFESI	50	63.16	8.505	1.203
	ILESI	50	63.84	5.250	.743
Finger@1month	TFESI	50	32.52	14.336	2.027
	ILESI	50	44.62	14.168	2.004
Finger@3month	TFESI	50	34.94	14.596	2.064
	ILESI	50	45.18	14.512	2.052
Finger@6month	TFESI	50	37.14	15.931	2.253
	ILESI	50	45.64	14.602	2.065
Finger@12month	TFESI	50	40.18	16.768	2.371
	ILESI	50	46.16	14.829	2.097
Satisfication@Pretreatment	TFESI	50	.26	.443	.063
	ILESI	50	.02	.141	.020
Satisfication@1month	TFESI	50	2.96	1.195	.169
	ILESI	50	1.94	1.316	.186
Satisfication@3month	TFESI	50	2.70	1.147	.162
	ILESI	50	1.78	1.282	.181
Satisfication@6month	TFESI	50	2.54	1.199	.170
	ILESI	50	1.76	1.287	.182
Satisfication@12month	TFESI	50	2.26	1.175	.166
	ILESI	50	1.70	1.282	.181
Visual @Pre treatment	TFESI	50	8.58	.538	.076
	ILESI	50	8.84	.370	.052
Visual@0	TFESI	50	3.30	2.197	.311
	ILESI	50	4.70	2.605	.368
Visual@15days	TFESI	50	3.74	2.284	.323
	ILESI	50	4.92	2.747	.388
Visual@1month	TFESI	50	4.02	2.369	.335
	ILESI	50	5.06	2.810	.397
Visual@3month	TFESI	50	4.06	2.469	.349
	ILESI	50	5.10	2.852	.403
Visual@6month	TFESI	50	4.32	2.543	.360
	ILESI	50	5.20	2.814	.398
Visual@1year	TFESI	50	4.58	2.635	.373
	ILESI	50	5.30	2.757	.390

Table 8- ROLAND MORRIS DISABILITY - MEAN SCORE ANALYSIS

Table 8A- ROLAND MORRIS DISABILITY MEAN SCORE ANALYSIS in TFESI

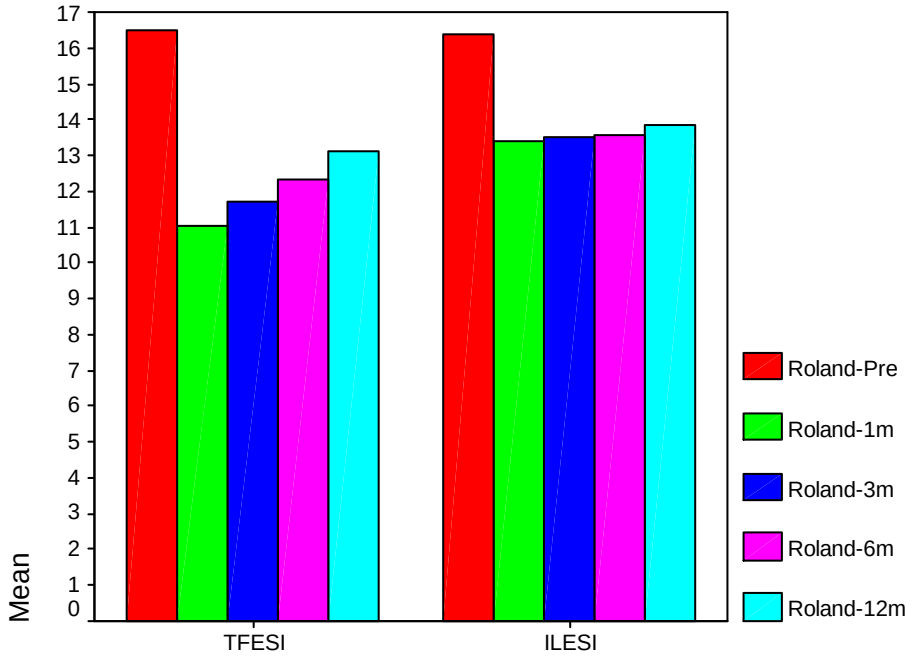
	Mean	SD
Roland-Pre treatment	16.52	2.00
Roland-1month	11.04*	2.58
Roland-3month	11.70**	2.56
Roland-6month	12.30	2.64
Roland-12month	13.14	2.83

*mean reduction of 5 scores of RMDQ significant at 1st month.

** mean reduction of almost 5 (4.82) by 3rd month

Table 8B- ROLAND MORRIS DISABILITY MEAN SCORE ANALYSIS in ILESI

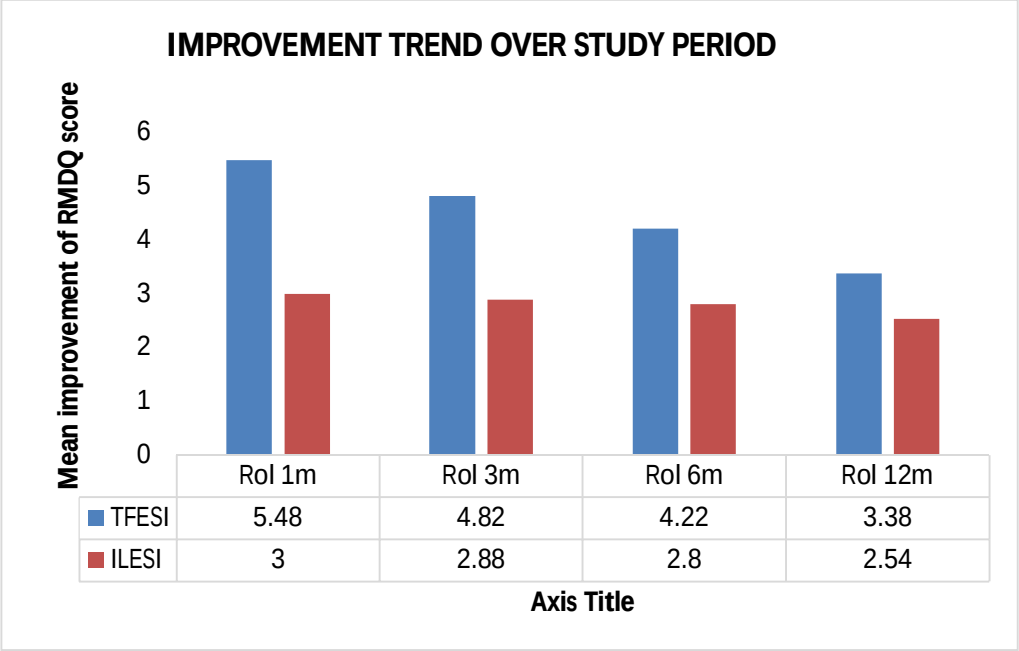
	Mean	SD
Roland-Pre treatment	16.38	1.41
Roland-1month	13.38	1.82
Roland-3month	13.50	1.88
Roland-6month	13.58	1.94
Roland-12month	13.84	2.06



Pre procedure Roland Morris Disability mean score was 16.52 and it got reduced to 11.04 by end of one month, was 11.70 by 3rd month, by 6th month 12.30 and by the end of the study period, the mean Roland-Morris score in TFESI was 13.14

In ILESI group, pre procedure Roland –Morris Disability mean was 16.38 and it got reduced to 13.38 by end of one month, was 13.50 by 3rd month, by 6th month 13.580and by the end of the study period , the mean Roland-Morris score was 13.84

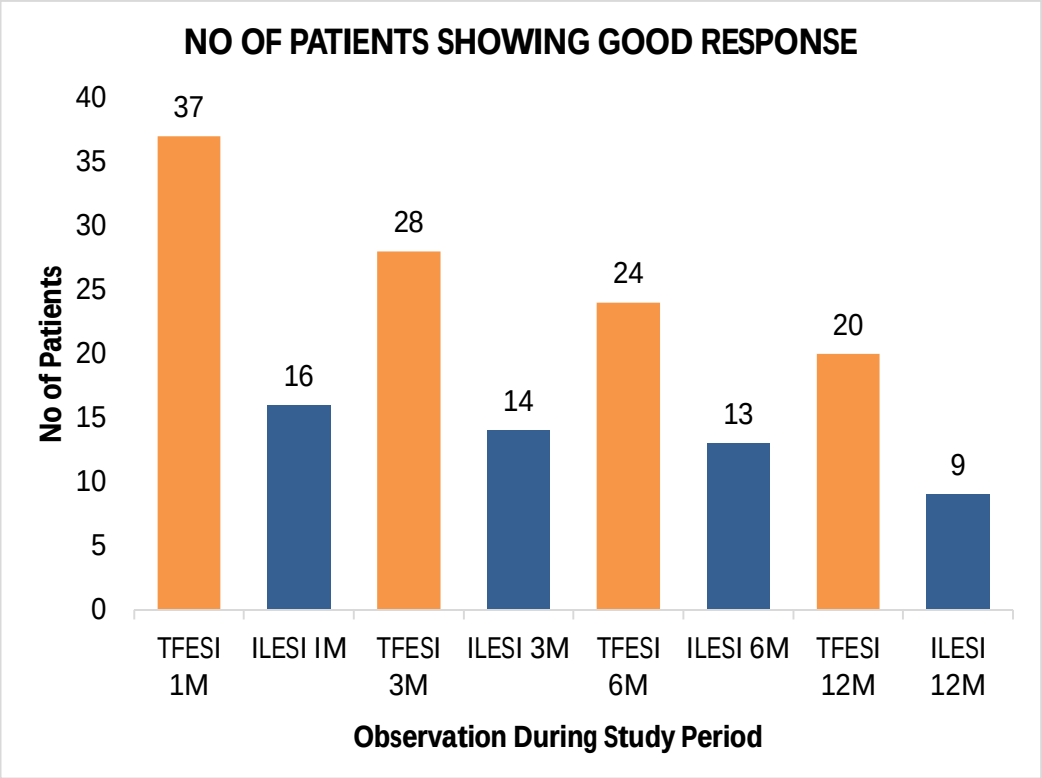
ROLAND MORRIS DISABILTY MEAN SCORE



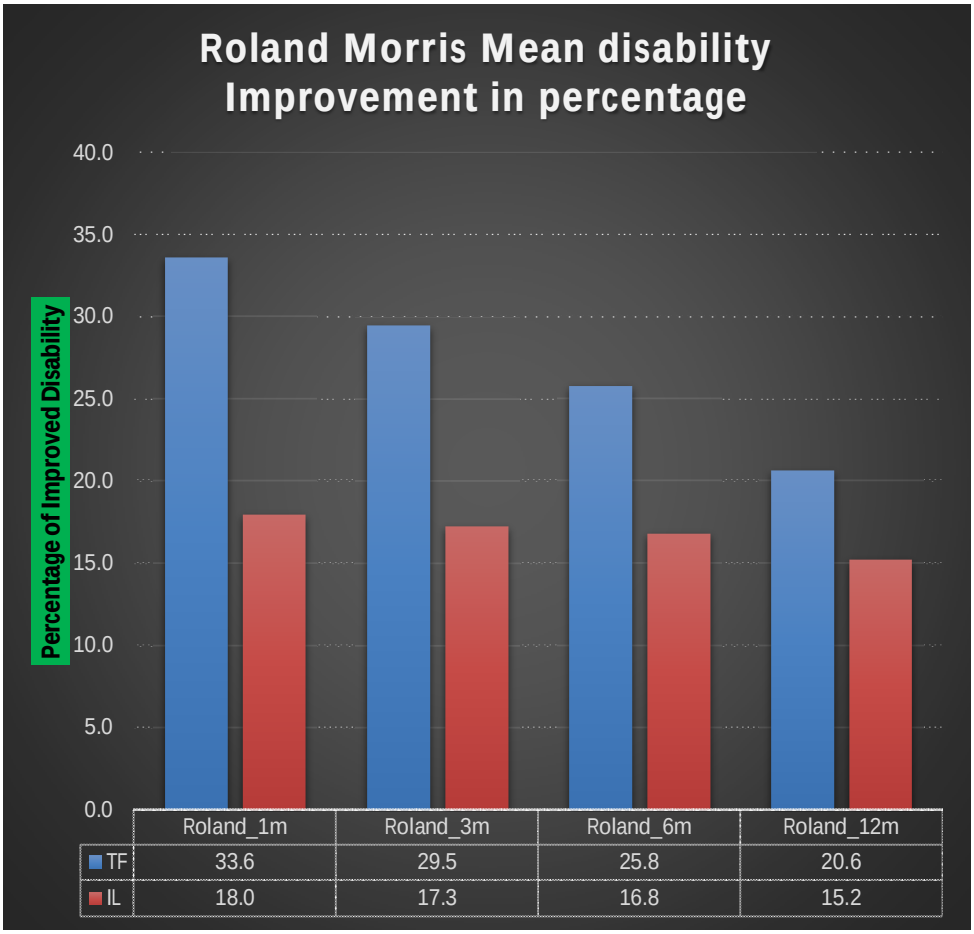
Reduction of 5 score or more after procedure considered significant. Only TFESI group achieved significant reduction in disability by mean

score of 5.48 by 1st month. Mean reduction was 4.82 for 3rd month, the mean reduction was 4.22 by 6 months. By 12 months mean reduction of disability was 3.38.

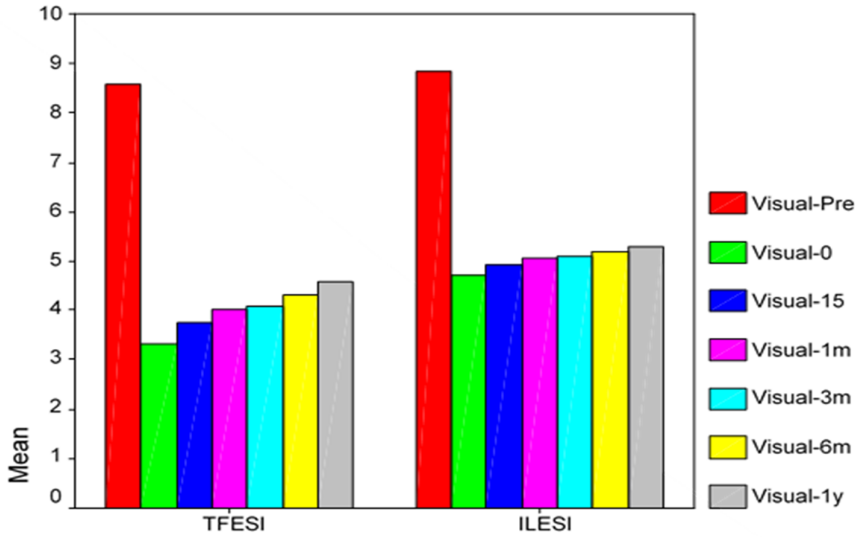
ILESI group reduction in disability mean score was 3.00 by 1 month. Mean reduction was 2.88 for 3rd month . The mean reduction was 2.80 by 6 months. By 12 months mean reduction of disability was 2.54.



No of patients showing good response by Roland Morris Disability Improvement


Roland Morris Mean disability
Improvement in percentage
Percentage of Improved Disability
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
Roland_1m
Roland_3m
Roland_6m
Roland_12m
TF
33.6
29.5
25.8
20.6
IL
18.0
17.3
16.8
15.2

VISUAL NUMERIC SCALE ASSESSMENT

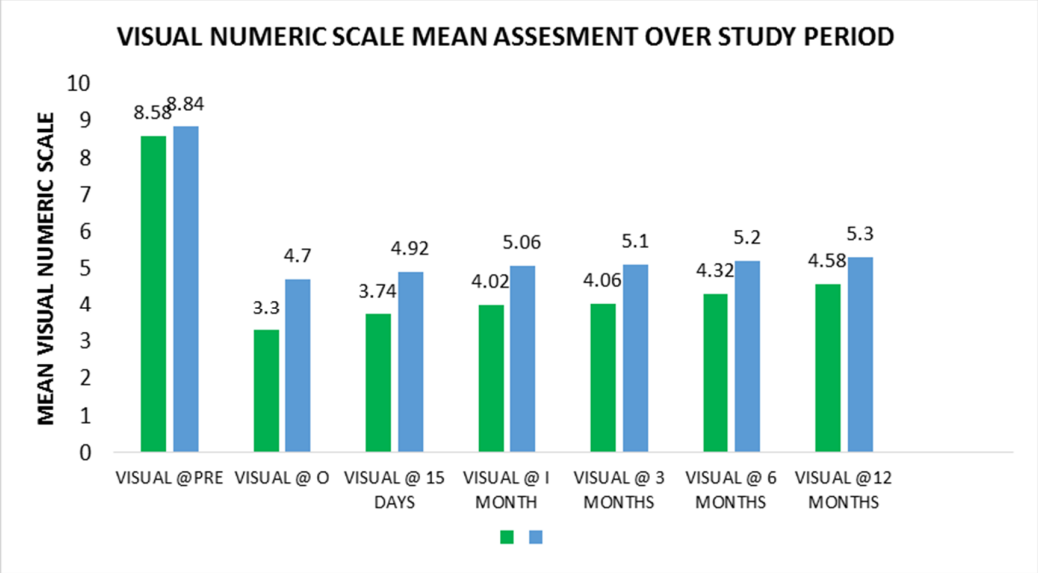


Visual numeric scale 9,10- worst pain. 1,2 – mild pain

In TFESI, the Visual Numeric Pain pre procedure mean was 8.58 and after procedure it got reduced to 3.3 immediately, 4.02 by end of one month, was 4.06 by 3rd month, by 6th month 4.32 and by end of the year was 4.58

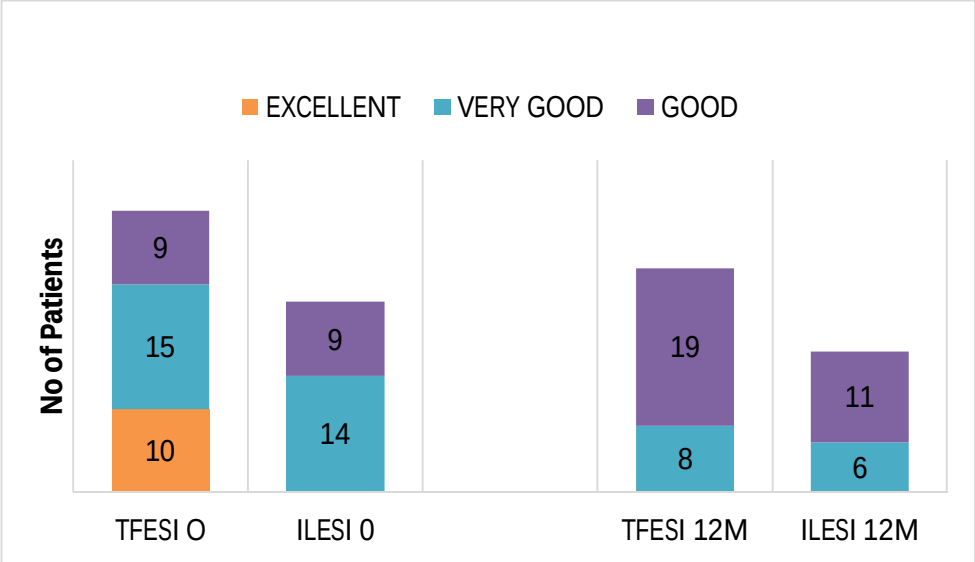
In ILESI, the Visual Numeric Pain pre procedure mean was 8.84 and after procedure it got reduced to 4.7 immediately, to 5.06 by end of one month, was 5.1 by 3rd month. By 6th month 5.2 and by end of the year was 5.3.

Fifty percent mean reduction was noticed only in transforaminal group till end of six months. Results were significant only in transforaminal group alone.



Visual numeric scale 9,10- worst pain. 1,2 – mild pain

VISUAL NUMERIC SCALE -RESPONDERS OVER TIME PERIOD



Excellent response - Visual Numeric Scale of 1

Very Good response - Visual Numeric Scale of 2

Good response - Visual Numeric Scale of 3.

In transforaminal group, 34 patients showed significant reduction in pain immediately, whereas in in ILESI group 27 patients showed significant reduction of pain immediately. But at the year end, 23 patients in TFESI and 17 patients in ILESI had a good pain relief. But excellent response of more than 80 percent reduction of pain noticed immediately in TFESI group vanished over the time period.

Ten patients in TFESI had excellent response of pain reduction by more than eighty percent (visual numeric scale of one). But by the end of six months only one patient was in visual numeric scale of one. But 27 patients in TFESI group had more than sixty percent reduction in pain by end of study period.

VISUAL NUMERIC SCALE - MEAN RESPONSE OVER TIME PERIOD

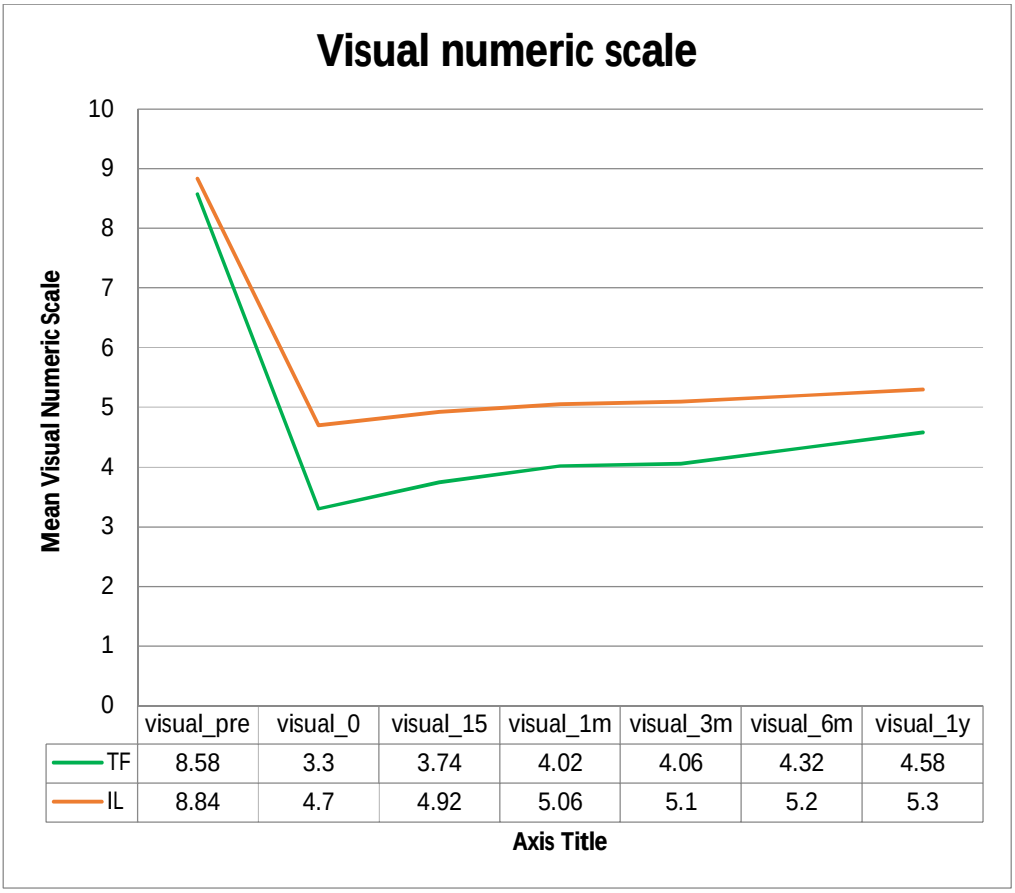
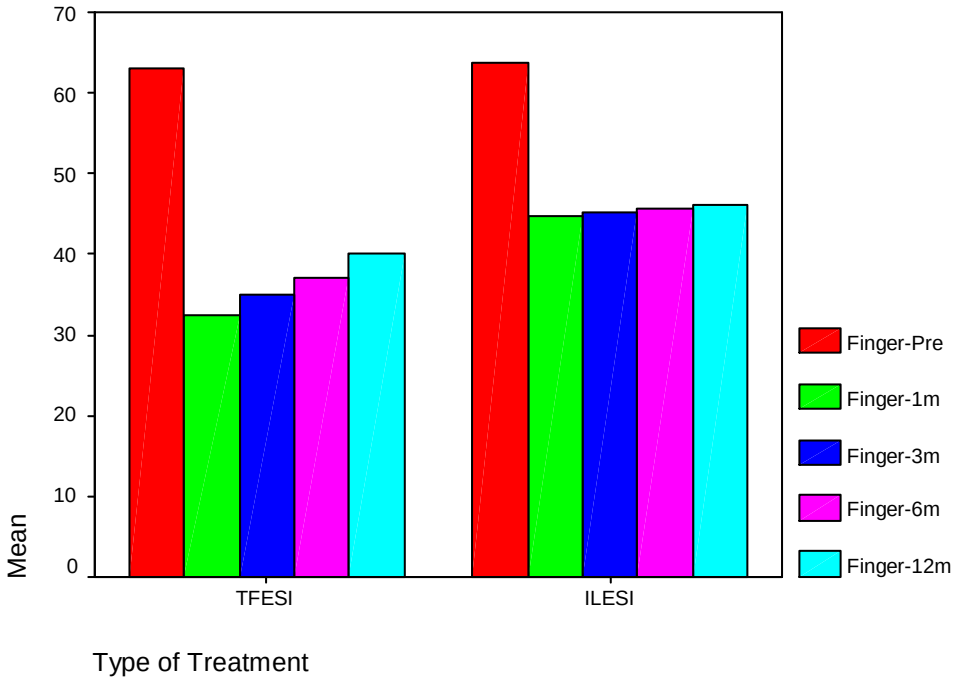


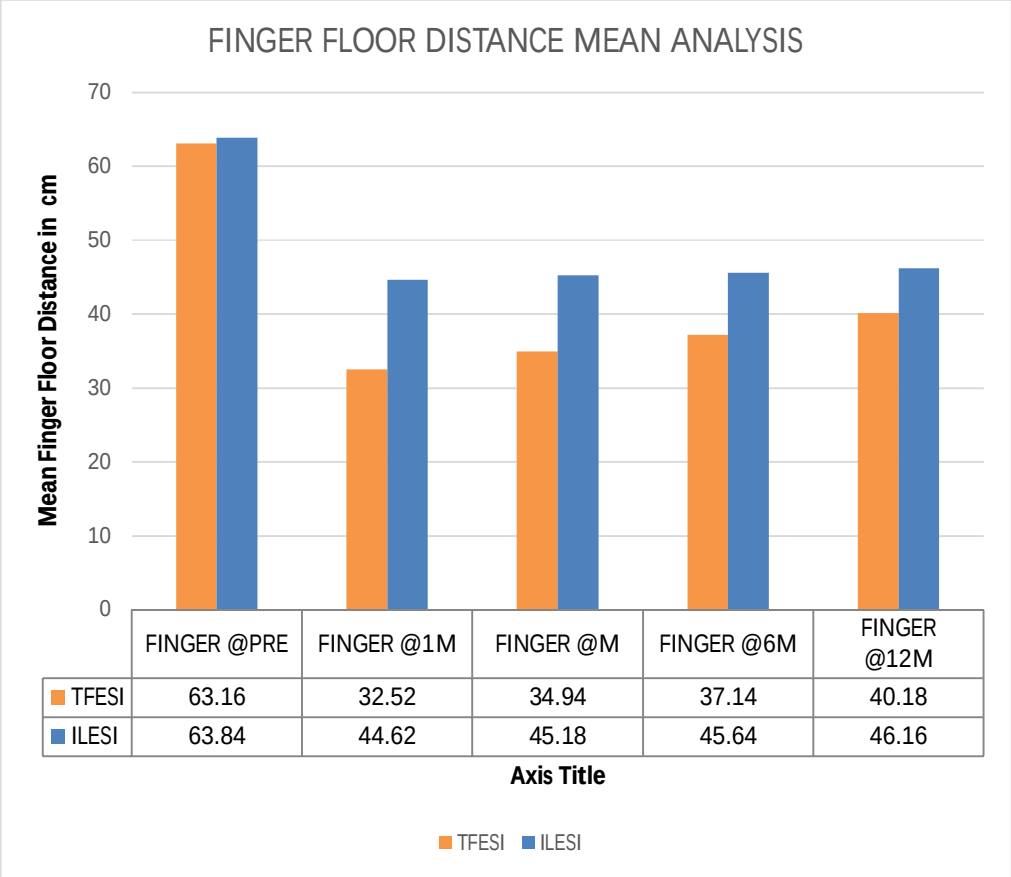
Diagram showing comparision of efficacy of TFESI & ILESI over a study period in pain relief. Chart showing immediate relief in pain and efficacy more in TFESI.

FINGER FLOOR DISTANCE ANALYSIS



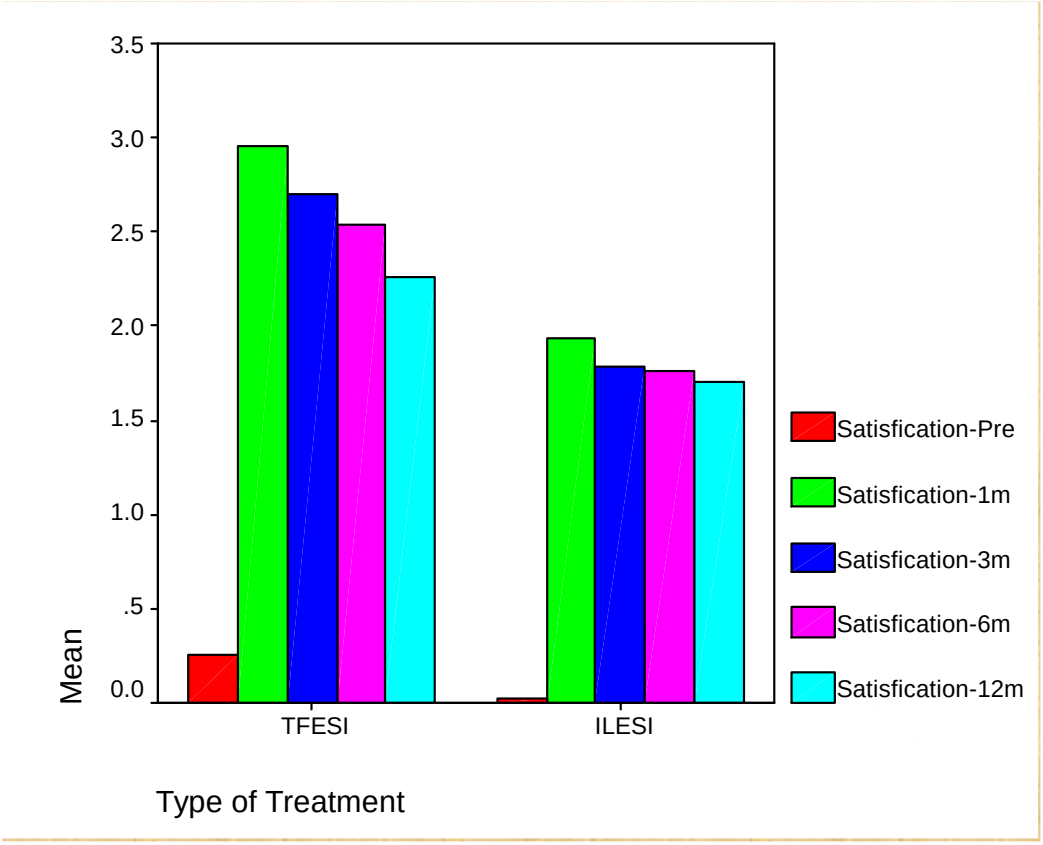
Pre procedure Finger to floor distance mean was 63.36 cm and it got reduced to 32.52 cm by end of one month, was 34.94 cm by 3rd month, by 6th month 37.14 and by the end of the study period, the mean in TFESI was 40.18 cm.

Pre procedure Finger to floor distance mean was 63.84 cm and it got reduced to 44.62 cm by end of one month, was 45.18 cm by 3rd month, by 6th month 45.68 and by the end of the study period, the mean in ILESI was 46.16 cm.



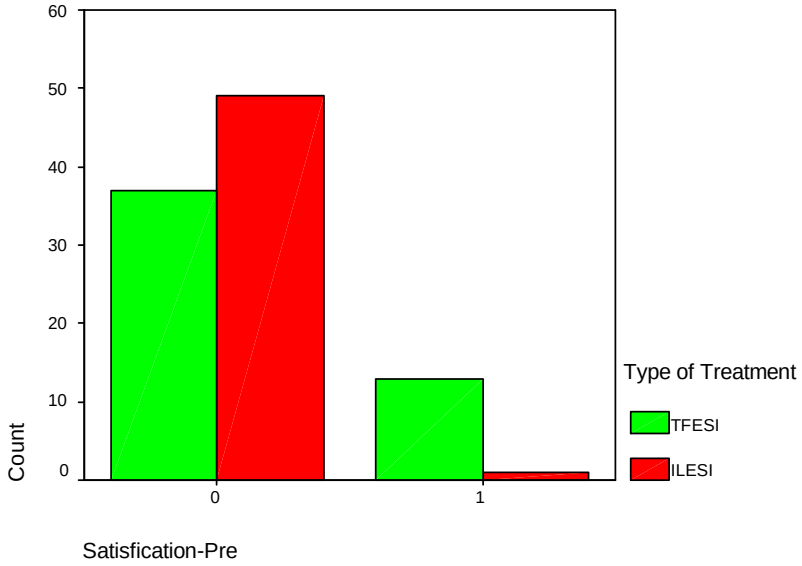
Mean improvent of 25 cm to floor distance noticed only in TFESI group. And improvement was seen up to six months. But by the end of study period it was 23 cm in TFESI which is also good improvement.

PATIENT SATISFACTION SCORE ANALYSIS



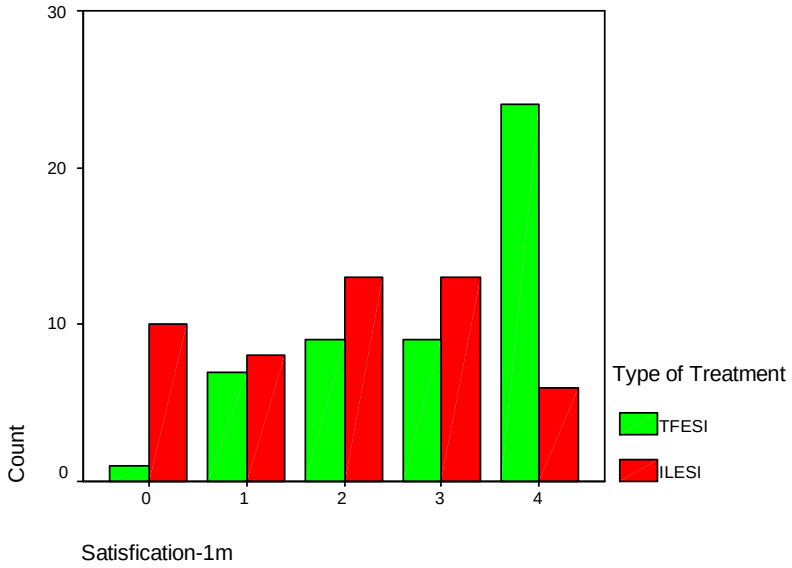
Patient satisfaction score - 0 (poor), 1 (fair), 2 (good), 3 (very good), and 4 (excellent)

PATIENT SATISFACTION SCORE PRIOR TO TREATMENT



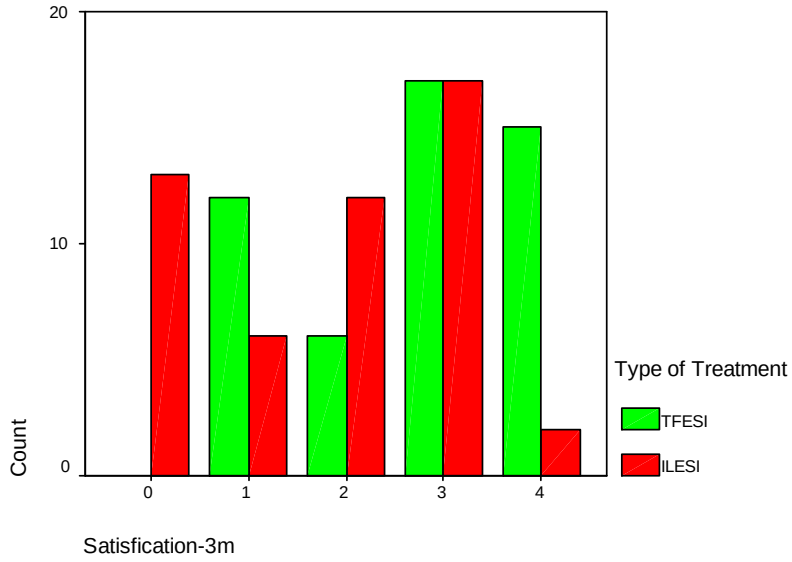
In TFESI group 37 and in ILESI group 49 patients were in poor response category prior to treatment.

PATIENT SATISFACTION SCORE RESPONSE I MONTH AFTER TREATMENT



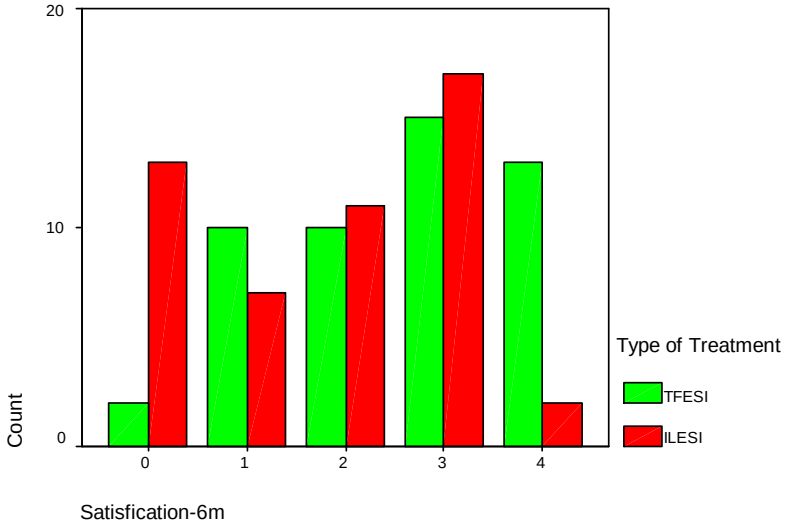
At 1 month after treatment 24 patients in TFESI group and 6 patients in ILESI group showed excellent satisfaction (score 4).

PATIENT SATISFACTION SCORE RESPONSE 3 MONTHS AFTER TREATMENT



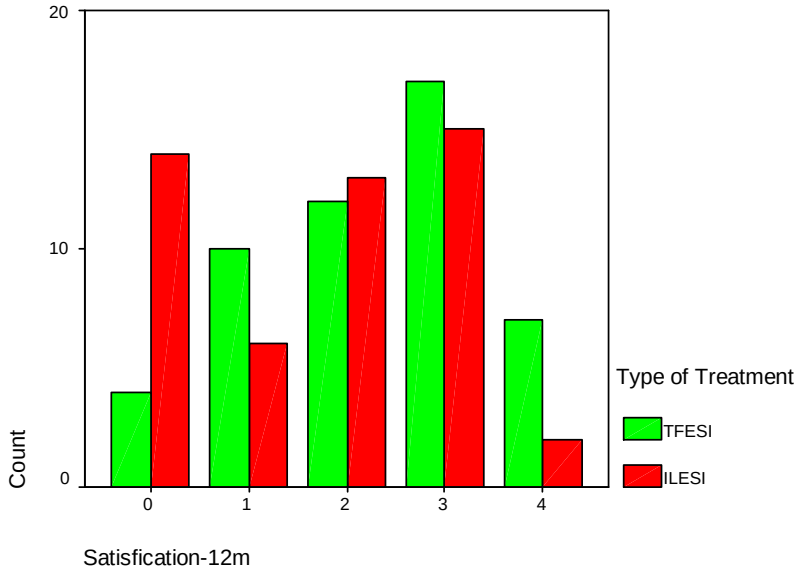
At 3 month after treatment 15 patients in TFESI group and 2 patients in ILESI group showed excellent satisfaction (score 4). 17 patients in TFESI group and 17 patients in ILESI group showed very good satisfaction (score 3).

PATIENT SATISFACTION SCORE RESPONSE 6 MONTHS AFTER TREATMENT



At 6 months after treatment 13 patients in TFESI group and 2 patients in ILESI group showed excellent satisfaction. 15 patients in TFESI group and 17 patients in ILESI group showed very good satisfaction.

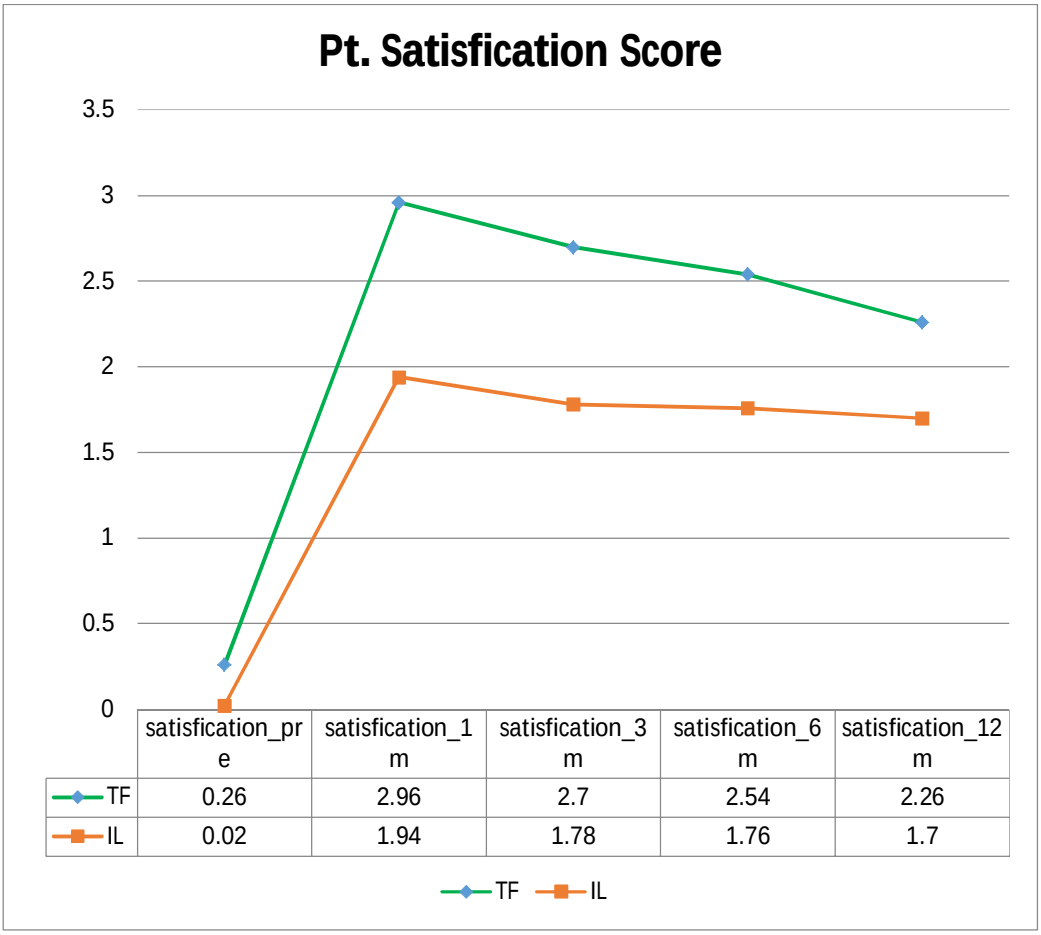
PATIENT SATISFACTION SCORE RESPONSE I2 MONTHS AFTER TREATMENT



At 12 months after treatment 7 patients in TFESI group and 2 patients in ILESI group showed excellent satisfaction. 17 patients in TFESI group and 15 patients in ILESI group showed very good satisfaction.

The Patient Satisfaction mean pre procedure in TFESI was 0.26 and after procedure it got improved to 2.96 by end of one month, slightly decreased to 2.70 by 3rd month with further declinement to 2.54 by 6th month and bye end of the year it was 2.26

The Patient Satisfaction mean pre procedure in ILESI was 0.02 and after procedure it got improved to 1.94 by end of one month, slightly decreased to 1.78 by 3rd month with further declinement to 1.76 by 6th month and by end of the year it was 1.70



Overall, 72% of the patients in Group 1 had a successful outcome, attaining maximal improvement within 4 weeks of treatment, overall improvement was 56% in ILESI group. Documented period of delay between final TFESI and improvement was 4 weeks.

The difference in outcomes between Groups 1 and 2 was statistically significant (*P* @ <0.001**). This difference was maintained throughout the duration of the study.

Factors associated with the unsuccessful outcome in Group 1 were presence of development of new degenerative spondylolisthesis in three patients and symptom

duration exceeding 1 year in 6 patients. However, statistical significance cannot be determined because of the small sample for each subgroup of patients.

Factors associated with the unsuccessful outcome in ILESI Group were presence of development of degenerative spondylolisthesis in five patients and symptom duration exceeding 1 year in 13patients. However, statistical significance cannot be determined because of the small sample for each subgroup of patients.

Table 9- **Independent Samples Test for descriptives**

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Roland@pre	Equal variances assumed	5.730	.019	.404	98	.687	.140	.347	-.548	.828
	Equal variances not assumed			.404	88.089	.687	.140	.347	-.549	.829
Roland@1month	Equal variances assumed	4.707	.032	-5.245	98	.000*	-2.340	.446	-3.225	-1.455
	Equal variances not assumed			-5.245	88.029	.000*	-2.340	.446	-3.227	-1.453
Roland@3month	Equal variances assumed	5.084	.026	-4.013	98	.000*	-1.800	.449	-2.690	-.910
	Equal variances not assumed			-4.013	89.898	.000*	-1.800	.449	-2.691	-.909
Roland@6month	Equal variances assumed	4.998	.028	-2.766	98	.007*	-1.280	.463	-2.198	-.362
	Equal variances not assumed			-2.766	90.010	.007*	-1.280	.463	-2.199	-.361
Roland@12month	Equal variances assumed	6.060	.016	-1.414	98	.161	-.700	.495	-1.683	.283
	Equal variances not assumed			-1.414	89.653	.161	-.700	.495	-1.684	.284

Finger@Pre	Equal variances assumed	8.095	.005	-.481	98	.632	-.680	1.414	-3.485	2.125
	Equal variances not assumed			-.481	81.608	.632	-.680	1.414	-3.492	2.132
Finger@1month	Equal variances assumed	.437	.510	-4.245	98	.000*	-12.100	2.850	-17.757	-6.443
	Equal variances not assumed			-4.245	97.986	.000*	-12.100	2.850	-17.757	-6.443
Finger@3month	Equal variances assumed	.282	.596	-3.518	98	.001*	-10.240	2.911	-16.016	-4.464
	Equal variances not assumed			-3.518	97.997	.001*	-10.240	2.911	-16.016	-4.464
Finger@6month	Equal variances assumed	.110	.741	-2.781	98	.006*	-8.500	3.056	-14.565	-2.435
	Equal variances not assumed			-2.781	97.266	.007*	-8.500	3.056	-14.565	-2.435
Finger@12month	Equal variances assumed	.634	.428	-1.889	98	.062	-5.980	3.166	-12.262	.302
	Equal variances not assumed			-1.889	96.556	.062	-5.980	3.166	-12.263	.303
Satisfication@Pre	Equal variances assumed	93.802	.000	3.649	98	.000	.240	.066	.109	.371
	Equal variances not assumed			3.649	58.881	.001	.240	.066	.108	.372
Satisfication@1month	Equal variances assumed	.221	.640	4.059	98	.000*	1.020	.251	.521	1.519

	Equal variances not assumed			4.059	97.100	.000*	1.020	.251	.521	1.519
Satisfication@3month	Equal variances assumed	1.170	.282	3.781	98	.000*	.920	.243	.437	1.403
	Equal variances not assumed			3.781	96.811	.000*	.920	.243	.437	1.403
Satisfication@6month	Equal variances assumed	.614	.435	3.136	98	.002*	.780	.249	.286	1.274
	Equal variances not assumed			3.136	97.514	.002*	.780	.249	.286	1.274
Satisfication@12month	Equal variances assumed	1.132	.290	2.278	98	.025*	.560	.246	.072	1.048
	Equal variances not assumed			2.278	97.265	.025*	.560	.246	.072	1.048
Visual@Pre	Equal variances assumed	29.550	.000	-2.815	98	.006	-.260	.092	-.443	-.077
	Equal variances not assumed			-2.815	86.925	.006	-.260	.092	-.444	-.076
Visual@0	Equal variances assumed	4.707	.032	-2.905	98	.005*	-1.400	.482	-2.356	-.444
	Equal variances not assumed			-2.905	95.288	.005*	-1.400	.482	-2.357	-.443
Visual@15	Equal variances assumed	6.585	.012	-2.336	98	.022*	-1.180	.505	-2.183	-.177
	Equal variances not assumed			-2.336	94.844	.022*	-1.180	.505	-2.183	-.177

Visual@1month	Equal variances assumed	7.454	.008	-2.001	98	.048*	-1.040	.520	-2.071	-.009
	Equal variances not assumed			-2.001	95.279	.048*	-1.040	.520	-2.072	-.008
Visual@3month	Equal variances assumed	6.637	.011	-1.949	98	.054	-1.040	.533	-2.099	.019
	Equal variances not assumed			-1.949	96.038	.054	-1.040	.533	-2.099	.019
Visual@6month	Equal variances assumed	3.886	.052	-1.641	98	.104	-.880	.536	-1.944	.184
	Equal variances not assumed			-1.641	97.012	.104	-.880	.536	-1.945	.185
Visual@1y	Equal variances assumed	1.438	.233	-1.335	98	.185	-.720	.539	-1.790	.350
	Equal variances not assumed			-1.335	97.799	.185	-.720	.539	-1.790	.350

Independent T test was performed to find the mean difference between two groups. (* means significant results). It is found that results are significant in **RMDQ** at 1month, 3rd month, 6th month and in **Finger Floor Distance** analysis at 1st month, 3rd month, 6th month and in **Patient Satisfaction Score** analysis at 1st month, 3rd month, 6th month, also in12th month and in **Visual Numeric Scale Assessment** in 1st month.

Table 10 Case Processing Summary					
Valid		**Missing**		**Total**	
N	Percent	N	Percent	N	Percent
100	100.0%	0	.0%	100	100.0%

Table 11 Chi Square Tests				
	Value	**df**	**Asymp. Sig. (2-sided)**	**Exact Sig. (2-sided)**
Pearson Chi-Square	.396[a]	1	.529	
Continuity Correction[b]	.176	1	.675	
Likelihood Ratio	.396	1	.529	
Fisher's Exact Test				.675
N of Valid Cases[b]	100			
a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 17.50.				
b. Computed only for a 2x2 table				

Table 12 Group Statistics					
	type@tr	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
RMDQ IMPROVEMENT @1month	TF	50	33.5809	11.27160	1.59404
	IL	50	17.9725	11.72675	1.65841
RMDQ IMPROVEMENT @3month	TF	50	29.4822	11.43955	1.61780
	IL	50	17.2642	11.82078	1.67171
RMDQ IMPROVEMENT @ 6month	TF	50	25.7802	11.99328	1.69611
	IL	50	16.8184	11.84312	1.67487
RMDQ IMPROVEMENT @12 month	TF	50	20.6310	13.44427	1.90131
	IL	50	15.2404	12.30675	1.74044

RMDQ- ROLAND-MORRIS LOW BACK PAIN DISABILITY QUESTIONNAIRE

Table 13 Independent Samples Test Levene's Test for Equality of Variances										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
RMDQ IMPROVEMENT @1month	Equal variances assumed	.172	.679	6.785	98	.000*	15.60842	2.30029	11.04358	20.17326
	Equal variances not assumed			6.785	97.847	.000*	15.60842	2.30029	11.04349	20.17335
RMDQ IMPROVEMENT @3month	Equal variances assumed	.132	.717	5.252	98	.000*	12.21794	2.32635	7.60138	16.83450
	Equal variances not assumed			5.252	97.895	.000*	12.21794	2.32635	7.60132	16.83456
RMDQ IMPROVEMENT @6month	Equal variances assumed	.003	.957	3.760	98	.000*	8.96176	2.38369	4.23141	13.69211
	Equal variances not assumed			3.760	97.984	.000*	8.96176	2.38369	4.23140	13.69212
RMDQ IMPROVEMENT @12month	Equal variances assumed	.359	.551	2.091	98	.039	5.39067	2.57761	.27548	10.50585
	Equal variances not assumed			2.091	97.244	.039	5.39067	2.57761	.27498	10.50635

RMDQ- ROLAND-MORRIS LOW BACK PAIN DISABILITY QUESTIONNAIRE

*Means significant results. Significant results noted in 1st month, 3rd month, and at 6th month.

DISCUSSION

Epidural steroid injections are given because

Abnormal concentrations of nociceptive
and inflammatory mediators around damaged nerve

chemical neuroradiculitis. [25,40]

Corticosteroids inhibit prostaglandin synthesis and block nociceptive C-fiber conduction. SAAL described high levels of Phospholipase A_2 level in lumbar disc herniation.[26]

Steroids classically work by the abolition of the rate-limiting step by the enzyme PLA_2 to liberate arachidonic acid from cell membranes.

No difference in outcome between males and females were noted. An initial successful outcome in 72% in TFESI group and 56% in ILESI group of the current patients was observed over an average follow-up period of 12 months.

Also, the results were obtained with an average of 1.42 & 1.6 steroid injections in group I & II respectively, which is significantly fewer than the traditionally prescribed 3 to 4 injections.

As per **Roland Morris Disability** improvement asssessment by first month 64% patients had significant reduction of disability in TFESI group whereas it was 32% for ILESI group. By the end of study period significant disability improvement persisted in 40% in TFESI group, it was 18% for ILESI group, which shows even though steroid effects detoriates over a period of time, percentage of people achieved persistent disability improvement for a significant period of 12 months were more in TFESI group.

As per **Visual Numeric Scale** 68% had very good relief of pain (VNS scale 1,2,3) immediately in TFESI group it was 46 percent for ILESI group. At the end of study period significant relief persisted in 54% in TFESI group and 34% in ILESI group. It shows pain relief of steroid starts very early and lasts longer than disability improvement.

As per **Patient Satisfaction Score** in TFESI group 64% had very good satisfaction by 1 month and by the end of study period it was 48% had very satisfied feel, whereas it was 38% for ILESI group initially and was 34% by end of the study period.

It shows effect of steroid detoriates over a time period in majority of patients due to progression of disease process. But significant number

patients have good response which last up to an year. The effect may continue for longer period for which further follow up needed.

More importantly, the patients in Group 1 attained maximal improvement in 2 weeks, as compared with 4 weeks in Group 2. Direct delivery of medication to the exact pathological site in the transforaminal approach coupled with the additional use of consistent rehabilitation may explain the longer duration of effect and the need for fewer injections.

Furthermore, the efficacy of ESIs may be explained by their presumed four mechanisms of action:

1. The steroid and anesthetic solution, both of which have anti nociceptive properties
2. The "nerve membrane–stabilizing properties of both the steroid and xylocaine
3. "The "washout" effect of the solution, which decreases the regional levels of inflammation mediators such as interleukin-1, tumor necrosis factor, and phospholipase A2
4. The potent anti-inflammatory properties of the steroid.,[26,28,41]

As per **NORTH AMERICAN SPINE SOCIETY (NASS)** opinion

1. No more than two injections be used to attempt to achieve a beneficial response in the first instance, and
2. Thereafter, it seems reasonable to use up to three injections in a six month period to reinstate and maintain benefit once it has been achieved.

In our study also we used only two injection but other studies they used 3-4 injections.

Pain improvement

As per **North American Spine Society (NASS)** 2013 opinion – "TFESI is recommended to provide relief of radicular pain. TFESI has been found to be effective in providing pain relief for at least one month in more than fifty percent of patients, with half of these patients continuing to benefit from treatment for a year or more." In our study also 34 patients (68 percent) had significant immediate relief. This effect persisted in 27 patients till the follow up period of 12 months.

Gahribo et al [32] study in 2011 showed pain improvement of 73.4% in TFESI group and 44.3% in ILESI group. But he followed patients only for 3 weeks. This result similar to our study which had similar results of significant pain relief as 68% and 46% initially (visual numeric scale group 1-3 mild pain)

As per North American Spine Society - "Karpinnen et al [43] study provides therapeutic evidence that: (1) LTFESI at four weeks after treatment achieves significantly greater improvements in pain and disability in patients with contained herniations, but not in patients with extrusions; and (2) for providing at least 75% relief of radicular pain." In our study also patients had significant improvement of more than 80 % reduction by one month.

But Kolsi et al [35] study did not find any difference in pain relief in both groups. Both groups had similar pain relief of 62.8% and 63.5%. His duration of study also 28 days. His study group had only 17 patients in group I and 13 patients in group II.

Ackerman and Ahmad [31] had 72% pain improvement by the end of 24 weeks in transforaminal group and 35.2% in interlaminar group. Out of 30 patients in transforaminal group 9 patients had complete pain relief. In our study also we found by 24 weeks, 15 patients with Visual Numeric Scale of one and two (Visual Numeric Scale 1-2 mild pain). Ackerman didn't use any numeric scale to assess pain. He divided patients into complete relief, partial relief and no relief.

Lee et al study pain relief by the end of one month was 78.0% and 64.5% in TFESI and ILESI respectively. By the end of 2 month results were 68.2% and 51.6% for TFESI and ILESI respectively.

Functional improvement

Rado et al study reported functional improvement as 28.3 in TFESI and 25.0 in ILESI group by the end of 24 weeks. In our study by the end of 6 months 48% in TFESI and 26% in ILESI group had significant disability improvement of five scales as per **Roland Morris low back pain Disability Questionarre.**

Similarly Chang et al in their study of "Transforaminal Versus Interlaminar Approaches to Epidural Steroid Injections: A Systematic Review of Comparative Studies for Lumbosacral Radicular Pain" found these two groups showed 15 percent difference in functional efficacy in TFESI comparing to ILESI for up to one to 6 months. In his reviewed articles follow up period was 2 weeks to 24 weeks.

Cooper et al[42] evaluating the effectiveness of LTFESI in 52 nonconsecutive patients with degenerative lumbar scoliotic stenosis and radiculopathy. Patients received, on average, 1.3 injections of 80 mg triamcinolone with 1.5 cc of 2% lidocaine and were followed for 85.5 weeks. Outcomes were measured by Numeric Rating Scale, NASS Patient Satisfaction Index and adapted Stucki Outcome Questionnaire pain and function scores. Successful outcome was defined as a patient satisfaction index of one or two, greater than two point improvement on

the NRS along with the summary pain and function scores. Success noted in 59.6% at one week, 55.8% at one month, 44.2% at three months, 37.2% at one year and 27.3% at two years.

Similarly **Hospital For Special Surgery - Spine** unit study had functional improvement of 14 percent disability improvement in TFESI group. In our study we had 20.6 percent mean disability improvement in TFESI group and 15.2 percent mean disability improvement in ILESI group by the end of study period.[38]

Riew et al [44] performed a prospective RCT to determine the effectiveness of selective nerve root injections. Of the 55 consecutive patients, 27 were randomly assigned to receive bupivacaine alone and 28 received bupivacaine with betamethasone. At mean follow-up of 23 months (13-28 months. The difference in operative rates between the two groups was significant with 67% of local anesthetic patients undergoing surgery compared to only 29% of corticosteroid plus anesthetic patients ($p<0.004$). Among patients with foraminal stenosis who avoided surgery, there was a significant decrease in neurological symptoms and low back pain on final evaluation. HIVD patients who avoided sugery showed a trend toward decreased back pain.

Ng et al [45] conducted a prospective RCT. Of the 86 consecutively assigned patients included in the study, 43 were randomly assigned to receive

LTFESI (bupivacaine + corticosteroid) and 43 received injections of bupivacaine alone. Outcomes were assessed at three months using the VAS and ODI along with patient satisfaction and change in walking distance. Intent to treat analysis did not demonstrate a statistically significant difference in Oswestry scores between the two treatment groups. In critique, this was a small study which was insufficiently powered to be an equivalence study.

Riew et al[46] five year follow up prospective comparative study assessing the efficacy of nerve root blocks for the treatment of lumbar radiculopathy. Of the 29 consecutively assigned patients included in the study, eight were lost to final follow-up. They gave local anaesthetics in one group and local anaesthetics with transforaminal steroid in another group. Majority of the patients who received steroid avoided surgery. They concluded that patients with lumbar radicular pain treated by means of transforaminal steroid therapy avoided surgical intervention for at least one year, will continue to avoid operative intervention for a minimum of five years. This study clearly shows the therapeutic effect and cost effectiveness. Hence our patients also need long term follow up.

Bogduk N et al[47] performed a prospective randomized controlled trial (RCT) assessing the efficacy of lumbar transforaminal epidural steroid injection (LTFESI) for radicular pain secondary to disc herniation. Of the 150 consecutively assigned patients included in the study, 28 received LTFESI with triamcinolone. Outcomes were assessed at one month and one year via the

Visual Analog Scale (VAS), SF-36 (version 1), Roland Morris Disability Questionnaire (RMDQ) and the Patient-Specified Functional Outcome instrument. Additionally work status and other health care services being utilized were assessed. The authors found that a significantly greater proportion of patients treated with transforaminal injection of steroid (54%) achieved pain relief compared to patients treated with transforaminal injection of local anesthetic (7%), transforaminal injection of saline (19%), intramuscular steroids (21%) or intramuscular saline (13%). Pain relief was corroborated by significant improvements in function and disability and reductions in use of other health care services. Outcomes were equivalent for patients with acute or chronic radicular pain. Over time, the number of patients who maintained relief diminished. Only some maintained relief beyond 12 months. In our study also we found relief diminishes over period of time.

Lee et al[48] described a retrospective comparative study assessing the effectiveness of interlaminar, caudal and transforaminal techniques with small and large volume of injectate in the treatment of lumbosacral HIVD or spinal stenosis. Of the patients included in the study, 54 received caudal injections, 64 received ILESI and 115 received LTFESI. Outcomes were assessed at two weeks, one month and two months using the VAS (Visual Analog pain Scale), Patient Satisfaction Index (PSI) and Roland Five Point Pain Scale. A higher ratio of successful results was found for translaminar and transforaminal techniques than caudal technique in VAS in the HIVD group and in VAS and PSI in the stenosis group. Reduction of Roland score was maintained until two

months in all techniques in the HIVD and stenosis groups. In the stenosis group, transforaminal groups showed more reduction of Roland score than caudal approach. No difference was found between small and large volume of transforaminal techniques. The authors concluded that the interlaminar and transforaminal approaches were more effective than the caudal approach for HIVD and stenosis groups. Effectiveness of the transforaminal approach was more prominent in the stenosis group as compared with the HIVD group. This study provides evidence that LTFESI is significantly more often effective than fluoroscopically-guided caudal injections, but is not significantly more often effective than fluoroscopically-guided interlaminar injection. It provides evidence that LTFESI provides at least 50% relief at two months after treatment in 66% of patients with radicular pain due to disc herniations and in 53% of patients with spinal stenosis.

Thomas et al[49] performed a prospective RCT to determine the first-line injection procedure to recommend for treatment of lumbar radiculopathy secondary to a disc herniation. Of the 31 consecutively assigned patients included in the study, 15 were treated with LTFESI and 16 received blind ILESI. Patients were assessed at six months with the VAS, RMDQ and Dallas Pain Questionnaire. Compared to the ILESI group the LTFESI patients had statistically significantly greater improvement in VAS at 30 days and six months, and daily activities, work and leisure activities, anxiety and depression and RMDQ scores at six months. The authors concluded that the efficacy of

LTFESI is greater than ILESI for the relief of lumbar radicular pain at 30 days and six months

NASS (**North American Spine Society**) states that presence of stenosis, size of HIVD, type of HIVD and hydration of HIVD do not predict outcome with LTFESI, but suggest that unsatisfactory results are statistically more likely in patients with higher grade herniation (displacement and entrapment of nerve root rather than abutment) and subarticular location of disc herniation.

Our study and other studies provide evidence that

1. LTFESI provides greater than 50% relief of pain in around 65% of patients for three months after treatment.
2. LTFESI is significantly more often effective than ILESI.
3. Relief of pain is associated with restoration of function and virtual elimination of the need for other health care.
4. 48% of patients undergoing LTFESI have relief that persists for at least 12 months, without repeat treatment;
5. LTFESI substantially reduces the need for surgery.

Fluoroscopic transforaminal epidural steroid injections appear to be an effective nonsurgical treatment option for patients with degenerative lumbar scoliotic stenosis and radiculopathy and should be considered before surgical intervention.

Fluoroscopy in TFESIs guides for precise delivery of the medication reliably to the interface between the HNP and the ventral aspect of the irritated nerve root.[17]

Without fluoroscopic guidance, there is a 30-40% chance of misplacing treatment into areas other than the epidural space at the site of herniation.[28] Also, use of a blind technique to deliver the steroid depends on normal anatomy of the epidural space.

Modification of the approach around the abnormal anatomy to the exact site of irritation on the side of the symptoms is necessary for adequate administration of the steroid–anesthetic combination.

This modification and site directed treatment cannot be accomplished without the use of fluoroscopy.

The absence of complications such as dural puncture and excessive bleeding commonly associated with blind epidural injection techniques attests to the safety of the fluoroscopic transforaminal approach.

Factors associated with the decreased success experienced by the steroid–anesthetic study group include development spondylolisthesis,

further progression of disc herniation and duration of symptoms exceeding 1 year.

The mechanical alteration of the disc–bone–nerve root interface in spondylolisthesis cannot be expected to change with the administration of epidural steroids.

The stretch of nerve root due to listhesis combined with a large disc herniation probably led to the 0% success rate for these patients, although the sample size was very small (n-8 in group 1 and n-20 in group II)

Short term response to TFESI may also predict a favorable surgical outcome.

Also, the patients with symptoms duration exceeding 1 year had only a 50% success rate. Irreversible changes related to chronic inflammation, including irritation, may take place with chronic neural compression, perhaps rendering the nerve root refractory to management with the local application of steroid.

The decreased success rate for patients with symptom duration exceeding 1 year may advocate for early initiation of transforaminal injection treatment.

ESI reduces economical burden for patients and health system. Also it avoids unnecessary surgical burden for patient.

From our study we found- Conservatively managed patients for a lumbar disc herniation will improve.

It is described as 80% may improve in literature. The exact percentage may vary.

The less success rate for patients with symptom duration exceeding 12 months advocates for early initiation of transforaminal injection treatment.

Even though Steroid effect detoriates over a time period in majority of patients due to progression of disease process, but significant number of patients have good response which lasts upto an year.

Pain relief effect of steroid starts very early and lasts longer than disability improvement.

The sample size is small. Large sample size is needed.

Duration of study also short, long term follow up needed.

CONCLUSION

From our study we conclude that

1. Epidural steroid injections are safe without any major adverse effects.
2. Patients with radicular pain from disc herniation or lumbar canal stenosis obtain significant relief from a preganglionic LTFESI irrespective of age, gender, level of injection, symptom duration and pain intensity.
3. Transforaminal epidural steroid therapy has better outcome with respect to Roland Morris disability assessment, Visual Numeric Scale, Finger Floor Distance assessment, Patient Satisfaction Score.
4. Transforaminal steroid injection is superior to ILESI as it gives target specific administration.
5. Interlaminar steroid administration is also useful if it is done under fluoroscopic guidance. But mostly it is given blindly and hence the chances of the needle misplacement are there, so lesser success rate.
6. Non responders rate is high in ILESI group.
7. Transforaminal group disablity improves significantly. Maximum improvement occurs with in one month. Further improvement rate diminishes. In majority of the patients response lasts more than year.
8. Patient Satisfaction and Pain Relief

- majority of the patients have a significant improvement which lasts more than year.

9. Lumbar transforaminal epidural steroid injections (LTFESI) are cost-effective.

Transforaminal epidural steroid treatment better medication for pain relief, patient satisfaction, disability improvement and functional improvement.

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Annexure

LIST OF ABBREVIATIONS USED

(In alphabetical order)

CT	:	Computed tomography
ESI	:	Epidural steroid
HNP	:	Herniated nuclosus pulposus
HIVD	:	Herniated intervertebral disc
IFT	:	Interferential Therapy
IL	:	Interlaminar
ILESI	:	Interlaminar epidural steroid
IVDP	:	Inter vertebral disc prolapse
LDD	:	lumbar disc disase
LBA	:	Low back ache
LS	:	Lumbo-Sacral
LTEFSI	:	Lumbar Transforaminal epidural steroid
MRI	:	Magnetic resonance imaging
RCT	:	Randomized control trial
TFESI	:	Transforaminal epidural steroid
TF	:	Transforaminal
TENS	:	Transcutaneous Electric Nerve Stimulation

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MASTER CHART

Sl No	Name	Age	IP No.	TREATMENT	Sex	Roland_pre	Roland_1m	Roland_3m	Roland_6m	Roland_12m	Finger_pre	Finger_1m	Finger_3m	Finger_6m	Finger_12m	Satisfication_p	Satisfication_1m	Satisfication_3m	Satisfication_6m	Satisfication_12m	Visual_pre	Visual_0	Visual_15	Visual_1m	Visual_3m	Visual_6m	Visual_1y	Second_dose
1	SYED AHAMED	33	150/15	TFESI	M	19	11	12	12	12	65	23	24	25	25	0	4	3	3	3	9	2	3	3	3	3	3	No
2	PUNITHA	45	999035	TFESI	F	17	10	11	11	12	67	21	23	25	25	0	3	3	3	2	8	3	3	3	3	4	4	No
3	RAJENDRAN	46	53818	TFESI	M	20	14	14	14	15	70	30	32	32	32	1	3	2	2	2	7	3	3	3	3	4	4	No
4	AHAMED	25	20115	TFESI	M	14	9	11	11	12	50	30	30	35	35	1	2	2	2	2	8	4	4	4	4	4	4	No
5	LAKSHMI	46	95832	TFESI	F	17	12	14	15	15	75	40	50	55	55	0	1	1	1	1	9	6	6	6	2	2	2	Yes
6	RAJA	52	100588	TFESI	M	16	9	10	11	12	65	30	30	35	35	0	4	3	2	2	9	1	2	3	3	3	3	No
7	AROKYA SAMY	47	90017	TFESI	M	16	8	9	9	10	65	19	25	25	28	0	4	3	3	2	9	2	2	3	3	3	3	No
8	ELANGOVAN	48	21768	TFESI	M	17	9	10	10	11	67	19	23	23	28	1	4	3	2	2	8	2	2	3	3	3	3	Yes
9	SOMESH	37	98887	TFESI	M	19	12	13	14	14	75	35	39	39	41	0	4	2	2	2	8	2	2	2	2	2	2	Yes
10	SRINI	61	99491	TFESI	F	18	13	14	14	15	73	35	35	41	41	1	4	4	3	3	8	2	2	3	3	3	3	No
11	SUBRAMANIYAM	62	94365	TFESI	M	16	11	12	12	13	68	23	27	27	29	0	3	3	3	3	8	3	3	3	3	3	3	No
12	ANNAMALAI	63	163/15	TFESI	M	17	16	16	16	17	70	65	65	68	68	0	1	1	1	1	8	6	6	6	6	7	8	Yes
13	PATCHAIAPPAN	56	101385	TFESI	M	17	15	15	17	18	75	69	69	75	75	0	0	1	1	1	9	8	8	7	8	8	8	Yes
14	PADMA	35	101794	TFESI	F	15	8	9	9	10	62	20	25	27	29	0	4	3	3	3	9	3	3	3	3	3	3	No
15	ELANGO	51	21788	TFESI	M	13	7	9	9	10	65	25	27	27	29	0	4	4	3	3	9	2	2	3	3	3	3	No
16	BHARATHI	37	20215	TFESI	F	18	14	15	16	17	70	60	60	65	70	0	1	1	1	1	9	8	8	8	8	8	9	Yes
17	PITCHAI	52	20315	TFESI	M	16	9	9	10	11	68	25	25	28	29	1	4	4	4	4	8	2	2	2	2	2	3	No
18	SRINI	32	104190	TFESI	M	16	13	13	14	15	65	55	55	59	59	0	2	1	1	1	8	5	6	6	6	7	8	Yes
19	MAHARUNISHA	60	20415	TFESI	F	18	16	16	17	18	70	65	65	65	69	1	1	1	1	1	9	8	8	8	9	9	9	Yes
20	SYED BASHA	64	10804	TFESI	M	13	8	8	8	9	55	25	25	26	27	0	4	3	3	3	8	2	2	2	2	2	3	No
21	KUMAR	45	20415	TFESI	M	17	11	11	12	12	65	32	32	35	37	1	4	4	4	4	9	1	1	1	1	1	2	No

22	JANAKI	30	70399	TFESI	F	19	12	13	14	15	80	45	46	47	47	0	4	3	3	3	9	2	2	2	2	3	3	No
23	MUNUSAMY	51	118415	TFESI	M	17	11	12	12	14	65	21	24	25	25	1	3	3	3	3	9	1	2	3	3	3	3	No
24	MANOHAR	49	20515	TFESI	M	12	6	6	7	7	40	15	16	18	19	0	4	4	3	3	8	3	3	3	3	3	3	Yes
25	GANESH KUMAR	49	20615	TFESI	M	16	9	9	10	10	57	19	23	23	23	0	4	3	3	2	9	1	4	4	4	4	4	No
26	JANAKI	30	70399	TFESI	F	15	12	12	13	14	65	45	47	57	65	0	1	1	4	4	9	8	8	8	8	8	9	Yes
27	MANIARASU	51	20515	TFESI	M	17	14	15	15	18	63	52	58	61	64	0	1	4	4	4	9	7	8	9	9	9	9	Yes
28	VINOTHKUMAR	58	78596	TFESI	M	19	11	12	12	13	56	21	22	22	28	0	3	3	3	3	8	2	2	2	3	3	3	No
29	TAMILSELVAN	48	20615	TFESI	M	14	8	8	11	12	45	24	25	25	35	0	3	3	2	1	8	3	3	3	3	3	4	No
30	KAMALA	54	10815	TFESI	F	16	9	9	10	11	52	29	30	30	30	0	4	4	4	3	9	2	2	2	2	2	2	No
31	APPAN NAIDU	46	20715	TFESI	M	19	13	14	15	16	68	41	43	45	47	0	2	2	2	1	9	3	4	4	4	4	4	No
32	VADIVEL	43	84715	TFESI	M	19	13	13	13	14	63	21	22	23	25	0	4	4	4	3	9	1	2	2	2	2	2	Yes
33	JOHNSON	37	20815	TFESI	M	16	13	13	14	15	52	39	41	45	50	0	2	2	2	2	8	4	4	4	4	5	8	Yes
34	DHANALAKSHMI	39	95747	TFESI	F	18	13	13	14	14	61	21	25	30	38	1	3	3	3	2	8	3	3	3	3	4	4	No
35	RAJNI	42	20915	TFESI	M	19	11	12	12	13	65	24	24	25	28	0	4	4	4	4	9	1	1	1	2	2	2	No
36	NARAYANAN	39	40674	TFESI	M	17	12	13	14	14	52	24	27	29	31	1	3	3	2	2	8	1	2	3	3	3	3	Yes
37	THIRUMURUGAN	38	58875	TFESI	M	15	12	14	15	15	54	40	45	48	55	0	2	1	0	0	9	7	8	8	9	9	9	Yes
38	RAM BABUNISHA	40	87407	TFESI	F	15	8	9	9	9	51	21	22	22	27	0	4	4	4	3	9	1	2	2	2	2	2	No
39	KRISHNAN	26	96349	TFESI	M	19	15	16	16	17	68	35	36	39	56	0	2	2	2	3	9	5	5	6	6	7	7	Yes
40	SAKTHIMURUGAN	41	59325	TFESI	M	13	8	9	9	9	45	21	23	24	25	1	4	4	4	3	8	2	2	2	2	3	3	No
41	ABAIRAM	53	74787	TFESI	M	19	11	11	12	12	68	21	23	23	25	0	4	4	4	3	9	1	1	2	2	2	2	No
42	SARASWATHY	53	87253	TFESI	F	20	17	17	18	19	69	51	53	59	68	0	2	1	1	0	9	6	7	7	8	9	9	Yes
43	SHANTHA	55	73110	TFESI	F	16	10	10	10	11	65	21	23	23	25	0	4	4	4	4	9	2	2	2	2	2	3	No
44	ILAMARAN	28	66651	TFESI	M	14	9	10	10	11	55	29	31	32	37	1	3	3	1	1	8	3	4	4	4	5	6	Yes
45	AYYANAR	55	95289	TFESI	M	17	13	14	15	17	69	55	59	65	68	0	2	1	0	0	9	5	8	9	9	9	9	Yes
46	MURALI	40	103964	TFESI	M	16	8	8	9	9	61	20	21	21	23	0	4	4	4	3	9	1	2	2	2	2	2	No
47	VALLI	35	102036	TFESI	F	17	11	11	12	12	69	19	20	21	23	0	4	4	4	4	9	2	2	2	2	3	3	No
48	SELVI	39	46539	TFESI	F	13	8	8	9	10	59	19	23	24	27	1	4	3	3	2	8	2	3	3	3	3	3	No
49	MALAONDIAH	43	73298	TFESI	M	15	9	11	12	14	67	45	54	55	65	0	2	1	1	1	9	5	6	8	8	9	9	Yes

50	RAJA	46	22490	TFESI		15	11	12	12	14	69	42	55	59	64	0	1	1	1	0	9	6	7	9	9	9	9	Yes
51	RENUKA	52	33346	ILESI	F	17	13	13	14	15	65	41	43	46	49	0	2	2	2	2	8	3	3	3	3	3	4	No
52	PACHAIPPAN	45	163/15	ILESI	M	18	14	14	14	14	69	41	42	42	43	0	3	3	3	3	9	3	3	3	3	3	4	Yes
53	PICHAIKANI	46	28529	ILESI	M	15	10	10	10	11	55	30	31	32	32	1	3	3	3	3	8	3	3	3	3	4	4	Yes
54	CHITRA	25	98257	ILESI	F	16	11	12	12	12	61	29	29	31	33	0	3	3	3	2	8	3	3	3	3	4	4	No
55	MUNIAPPAN	46	35637	ILESI	M	17	14	15	16	17	63	52	55	59	63	0	1	1	1	0	9	6	7	8	9	9	9	Yes
56	SARASWATHY	52	87253	ILESI	F	18	13	13	13	13	65	30	31	31	31	0	3	3	3	3	9	2	2	2	2	3	3	No
57	KALLANI	61	44550	ILESI	F	17	12	12	12	12	63	31	31	31	31	0	4	3	3	3	8	2	2	2	2	2	3	No
58	DURAIRAJ	48	48612	ILESI	M	19	15	16	17	19	70	50	62	62	68	0	2	2	1	1	9	6	6	7	8	9	9	Yes
59	RANI	34	100443	ILESI	M	15	15	15	15	15	65	65	65	65	65	0	0	0	0	0	9	8	9	9	9	9	9	Yes
60	SRINIVASAN	56	77888	ILESI	M	17	11	11	11	11	65	25	25	25	25	0	4	4	4	4	9	2	2	2	2	2	2	No
61	JEYA	45	42917	ILESI	F	14	14	14	14	14	59	59	59	59	59	0	0	0	0	0	9	9	9	9	9	9	9	Yes
62	BHARATHI	34	44086	ILESI	F	17	15	15	15	15	68	58	58	58	58	0	2	1	1	1	9	5	6	6	6	6	7	Yes
63	GANESAN	51	22346	ILESI	M	17	12	12	12	12	60	28	28	28	28	0	3	3	3	3	8	2	2	2	2	2	2	No
64	VIMALA	44	115868	ILESI	F	16	15	15	15	15	60	58	58	58	60	0	1	0	0	0	9	7	8	9	9	9	9	Yes
65	MANI	60	970	ILESI	M	17	12	12	12	12	65	35	35	35	35	0	2	2	2	2	9	3	3	3	3	3	3	No
66	JEGANATHAN	37	103493	ILESI	M	16	13	13	13	13	68	45	47	47	47	0	2	2	2	2	9	4	4	4	4	4	4	Yes
67	PARIMALA	31	48218	ILESI	F	15	10	10	10	11	50	30	30	30	31	0	3	3	3	3	9	3	3	3	3	3	3	No
68	RAJAMANICKAM	49	9648	ILESI	M	17	16	17	17	19	69	65	68	69	69	0	1	0	0	0	9	8	9	9	9	9	9	Yes
69	RAJU	21	19161	ILESI	M	16	12	12	12	12	69	36	36	36	36	0	2	2	2	2	9	4	4	4	4	4	4	yes
70	KRISHNAVENI	60	50930	ILESI	F	14	14	14	14	14	68	68	68	68	68	0	0	0	0	0	9	9	9	9	9	9	9	Yes
71	SELVARAJ	42	19147	ILESI	M	16	11	12	12	12	59	30	30	31	32	0	4	3	3	3	9	3	3	3	3	3	3	No
72	SRINVASAN	26	29972	ILESI	M	17	16	17	17	17	65	63	65	65	65	0	1	0	0	0	9	7	9	9	9	9	9	Yes
73	LAKSHMIBAI	55	114002	ILESI	F	15	13	13	13	13	59	55	55	55	55	0	1	1	1	1	9	7	7	7	7	7	7	Yes
74	JEYAMANI	43	110817	ILESI	M	17	12	12	12	12	64	25	25	25	25	0	3	3	3	3	9	2	2	2	2	2	2	No
75	SELVI	46	56428	ILESI	F	19	14	14	14	15	69	35	35	37	37	0	3	3	3	3	9	2	2	3	3	3	3	No
76	REVATHI	46	53877	ILESI	F	15	15	15	15	16	56	56	56	56	58	0	0	0	0	0	9	9	9	9	9	9	9	Yes
77	JEGANATHAN	24	103493	ILESI	M	16	13	13	13	13	60	35	35	35	35	0	2	2	2	2	9	3	4	4	4	4	4	Yes

78	SETHU	63	20815	ILESI	M	19	15	15	15	15	70	39	39	40	40	0	3	3	3	2	9	2	2	2	2	3	3	No
79	SASIKALA	23	54430	ILESI	F	16	16	16	16	16	59	59	59	60	60	0	0	0	0	0	8	8	8	8	8	8	8	Yes
80	BABY	45	67230	ILESI	F	17	14	14	14	14	65	39	39	39	39	0	2	2	2	2	9	3	3	3	3	3	3	Yes
81	MURUGESAN	55	55901	ILESI	M	15	11	11	11	12	70	40	40	42	44	0	4	3	3	3	9	2	3	3	3	3	3	No
82	MALARKODI	51	42802	ILESI	F	13	10	10	10	10	51	23	23	23	23	0	2	2	2	2	9	4	4	4	4	4	4	Yes
83	VASANTHA	45	77556	ILESI	F	16	16	16	16	16	69	69	69	69	69	0	0	0	0	0	9	9	9	9	9	9	9	Yes
84	RANGANATHAN	49	21015	ILESI	M	17	14	14	14	14	65	51	51	52	52	0	1	1	1	1	9	7	7	7	7	7	7	Yes
85	ARIVALAAGAN	56	21115	ILESI	M	18	14	14	14	14	68	32	32	32	33	0	3	3	3	3	9	2	2	2	2	2	3	No
86	PAPPA	50	103591	ILESI	F	14	14	14	14	14	55	55	55	55	55	0	0	0	0	0	9	9	9	9	9	9	9	Yes
87	PACHAIMUTHU	47	90917	ILESI	M	18	15	15	15	15	69	45	45	45	45	0	2	2	2	2	9	4	4	4	4	4	4	Yes
88	AROKYADOSS	61	20915	ILESI	M	17	12	12	12	12	65	29	29	29	29	0	4	4	4	4	8	2	2	2	2	2	2	No
89	GANDHIMATHY	47	20121	ILESI	F	16	16	16	16	16	60	60	60	60	60	0	0	0	0	0	9	9	9	9	9	9	9	Yes
90	JAMU	24	70228	ILESI	M	15	12	12	12	12	55	39	39	39	39	0	2	2	2	2	9	4	4	4	4	4	4	Yes
91	THANIGAI	56	21015	ILESI	M	16	11	11	11	11	59	30	30	30	30	0	3	3	3	3	9	2	2	2	2	2	2	No
92	RADHA	32	28377	ILESI	F	14	14	14	14	14	65	65	65	65	65	0	0	0	0	0	9	9	9	9	9	9	9	Yes
93	KARTHIK RAJA	23	78326	ILESI	M	17	14	14	14	14	67	54	54	54	54	0	2	2	2	2	9	4	4	4	4	4	4	No
94	VEERAMANI	31	55836	ILESI	M	18	16	16	16	16	69	61	61	61	62	0	1	1	1	1	9	6	7	7	7	7	7	Yes
95	KALIDOSS	30	22911	ILESI	F	19	14	14	15	15	70	35	35	35	35	0	4	3	3	3	9	2	2	2	2	2	2	yes
96	JEGAN	35	114201	ILESI	M	17	15	15	15	15	70	55	55	55	55	0	2	2	2	2	9	4	4	4	4	4	4	Yes
97	SANGEETHA	56	49436	ILESI	F	17	11	11	11	11	70	25	25	25	25	0	3	3	3	3	9	2	2	2	2	2	2	yes
98	ELUMALAI	37	48708	ILESI	M	15	13	13	13	14	65	60	61	65	65	0	1	1	1	1	9	6	7	9	9	9	9	Yes
99	INDRA	41	51502	ILESI	M	16	16	16	16	16	62	62	62	62	62	0	0	0	0	0	8	8	8	8	8	8	8	No
100	SRINIVASAN	42	24489	ILESI	M	16	11	11	11	12	65	29	29	29	29	0	3	3	3	3	9	2	2	3	3	3	3	No

INFORMATION SHEET

Principle Investigator Name :

Participant Name :

We are conducting a study on **COMPARATIVE STUDY OF FUNCTIONAL EFFICACY OF TRANS FORAMINAL VS INTERLAMINAR EPIDURAL STEROID INJECTION FOR LUMBAR DISC DISEASE"**among patients attending the Institute of Orthopaedics & Traumatology, Rajiv Gandhi Government General Hospital, Chennai and for that your specimen may be valuable to us.

The purpose of this study is to evaluate and compare, the clinical, and functional outcome of LUMBOSACRAL PAIN treated by transforaminal and interlaminar epidural steroid injection. We are selecting certain cases and if you are found eligible, we may be using your radiographs of the lumbo sacral spine to document which in any way do not affect your final report or management.

All the procedures are free of cost and there will not be any side effects by using this plate.

The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of Investigator Signature of Participant

Date :

Place :

PATIENT CONSENT FORM

Study Detail : **“““COMPARATIVE STUDY OF FUNCTIONAL EFFICACY OF TRANS FORAMINAL VS INTERLAMINAR EPIDURAL STEROID INJECTION FOR LUMBAR DISC DISEASE”**

Study Centre : Rajiv Gandhi Government General Hospital, Chennai.

Patient’s Name :

Patient’s Age :

Identification Number :

Patient may check (√) these boxes

a) I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ❑

b) I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ❑

c) I understand that sponsor of the clinical study, others working on the sponsor’s behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ❑

d) I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms. ❑

e) I hereby consent to participate in this study. ❑

f) I hereby give permission to undergo detailed clinical examination, Radiographs & blood investigations as required. ❑

Signature/thumb impression

Patient’s Name and Address:

Signature of Investigator

Study Investigator’s Name:
Dr. B.Saravanan

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. B. Saravanan
Post Graduate in M.S. (Orthopaedics)
Madras Medical College,
Chennai-3.

Dear Dr. B. Saravanan,

The Institutional Ethics Committee has considered your request and approved your study titled **"COMPARATIVE STUDY OF FUNCTIONAL EFFICACY OF TRANS FORAMINAL VS INTERLAMINAR EPIDURAL STEROID INJECTION FOR LUMBAR DISC DISEASE" No. 09092015.**

The following members of Ethics Committee were present in the meeting held on **08.09.2015** conducted at Madras Medical College, Chennai-3.

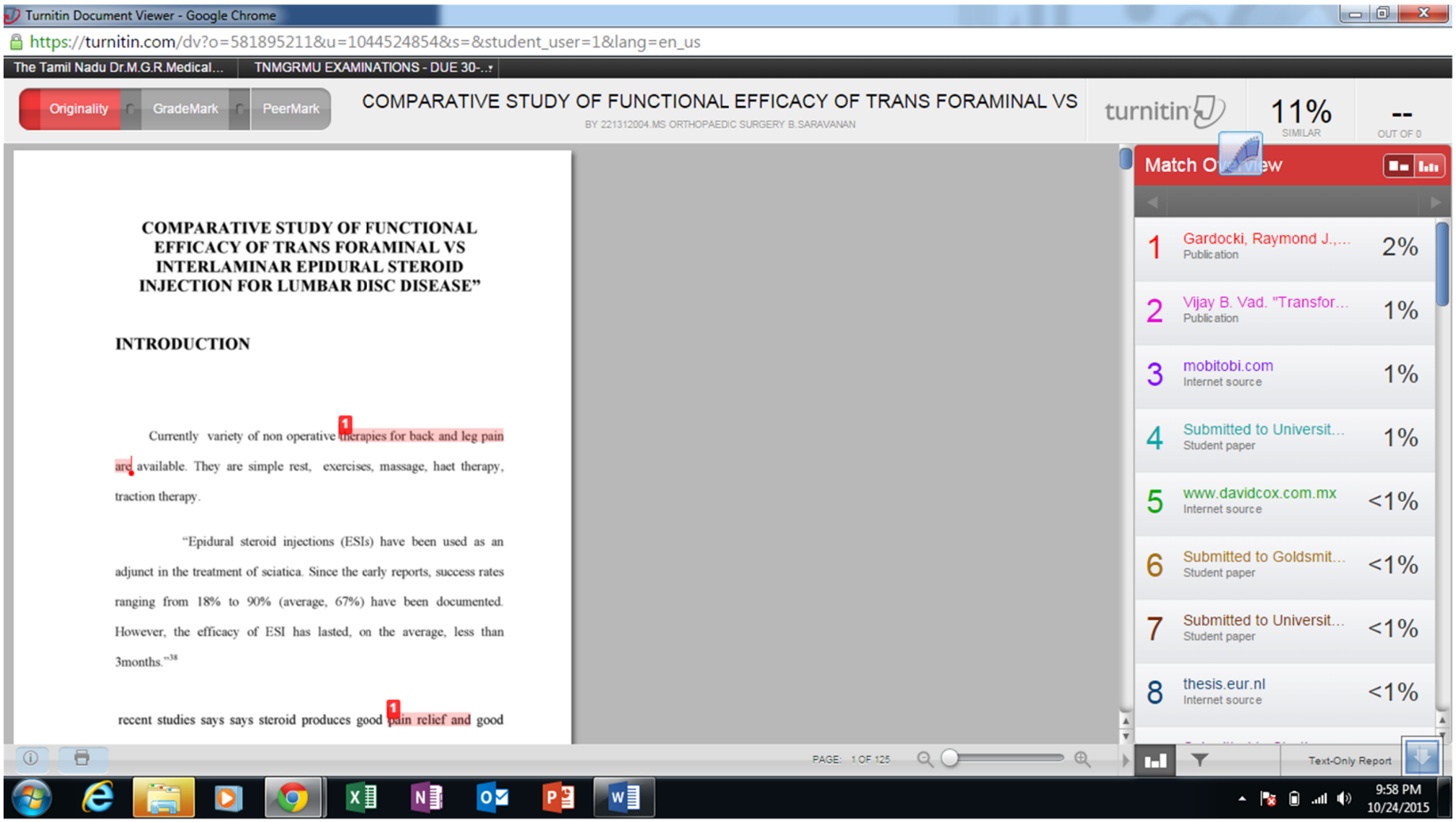
1. Prof.C.Rajendran, M.D.	: Chairperson
2. Prof.R.Vimala, M.D., Dean, MMC, Ch-3	:Deputy Chairperson
3. Prof.Sudha Seshayyan, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4. Prof.B.Vasanthi, M.D., Professor Pharmacology, MMC	: Member
5. Prof.P.Ragumani, M.S., Professor, Inst.of Surgery, MMC	: Member
6. Prof. Amudhavalli, Prof. of Biochemistry, MMC	: Member
7. Prof.Srinivasagalu, Director, Inst.of Inter Med. MMC	: Member
8. Tmt. J. Rajalakshmi, JAO, MMC	: Lay Person
9. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
10. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003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COMPARATIVE STUDY OF FUNCTIONAL EFFICACY OF TRANS FORAMINAL VS INTERLAMINAR EPIDURAL STEROID INJECTION FOR LUMBAR DISC DISEASE"
INTRODUCTION
Currently variety of non operative therapies for back and leg pain are available. They are simple rest, exercises, massage, haet therapy, traction therapy.
"Epidural steroid injections (ESIs) have been used as an adjunct in the treatment of sciatica. Since the early reports, success rates ranging from 18% to 90% (average, 67%) have been documented. However, the efficacy of ESI has lasted, on the average, less than 3months."[38]
recent studies says says steroid produces good pain relief and good
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